

# **Christina Pramudji**

## **General Materials List**

***in Addition to Materials Referenced in Report***

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Zhong, Chen. [Pop 187] Comparison of three kinds of mid-urethral slings for surgical treatment of female SUI. <i>Urologia</i> 2010; 77(1): 37-42
Zhu L, et al. [Pop 21, 18-60 mos, median 43.5 mo fu] Modified laparoscopic sacrocolpopexy with mesh for severe pelvic organ prolapse. <i>Int J Gynecol Obstet</i> 121 (2013) 170-172.
Zhu L, Lang J, Hai N, Wong F. Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence. <i>Int J Gynaecol Obstet</i> 2007; 99: 14-17.

**Medical Literature**

Zullo MA, Plotti F, Calcagno M, et al. One-year follow-up of tension-free vaginal tape (TVT) and Transobturator suburethral tape from inside to outside (TVT-0) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007; 51: 1376-1382; discussion 1383-1384.

Zyczynski H. [AUA Abs 1354] A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. J Urol 2009; 181: 483.

Zyczynski H. Sexual activity and function in women more than 2 years after midurethral sling placement. Am J Obstet Gynecol 2012; 207: 421.e1-6.

Zyczynski HM. (Prosima Study investigators) One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol 2010; 203: 587.e1-8

## Production Materials

<b>Document Description [Bates Range]</b>
000001_4275674_d_Use of Gynemesh PS in Prolapse Surgery Power Point
2000 June TVT Surgeons Resource Monograph
2003 Gynemesh PS Early Clinical Experience White Paper
2003 Gynemesh PS white paper. Gynemesh PS Early Clinical Experience.
2004 Gynemesh PS Study Poster - AUGS 2004 San Diego. Luente V, Hale D, Miller D, Madigan J. A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse.
2005 Prolift Prof Ed Slide deck (P's Exhibit 127)
2005-2006 Gynecare Prolift Pelvic Floor Repair Systems - slides (16 pages)
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
2007 & 2008 Gynecare Prolift Pelvic Floor Repair Systems - slides (46 pgs)
2007 Prolift Prof Ed Slide deck (P's Exhibit 128)
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
9.22.2011 Letter to surgeons
A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse by V. Luente, et al. 1 pg
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
Australian Pelvic Floor Discussion
Benefit Risk Profile of Transvaginal Mesh Products Used for the Treatment of Pelvic Organ Prolapse signed by Piet Hinoul dated 6/21/2012
Brigette Fatton Powerpoint Presentation entitled "Complications in Pelvic Floor Dysfunction Surgery: evaluation and management.
Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2005 (8 pgs)
Brochure Treatment Options for Pelvic Organ Prolapse Stop coping. Start living. Dated in 2008 Gynecare Prolift (15 pgs)
Classification Website Intro "An International Urogynecological Association (IUGA)/Internation Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertionm of Prostheses (Meshes, Implants, Tapes) & Grafts in Female Pelvic Floor Surgery."
Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013
Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.
D00001256-2005 Prolift Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems) [Native Format]
D00001260-2007 and 2008 Prolift and M Prof Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems)[Native Format]
Dear Surgeon Letter from Piet Hinoul and Aaron Kirkemo.
Declaration of Reynaldo Librojo
Declaration of Reynaldo Librojo in Support of Motion for Summary
Declaration of Thomas A. Barbolt, Ph.D., DABT, 1981-2011 in Support of Motion for Summary Judgement
DEFT 19.1-19.6 - Prolift M IFU
DEFT 730.1-730.72 - 2007 Prolift Surgeons Monograph
DEPO.ETH.MESH.00004755 - Guidoin Explant
Document entitled "Delay in Prosima Activities"

## Production Materials

Document entitled "Pelvic Floor Repair. Extended Review of Medical Literature."
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2
Email string re - Revised write up of the DeLeval and Waltregny visit
Email string re: Ultrapro vs Prolene Soft Mesh
Email string, top one from Gary Pruden to David Robinson, et al. re: article entitled :Vaginal repair with mesh no better than colporrhaphy for pelvic organ prolapse.
ETH MESH 00082651-54
ETH MESH 07903682-83
ETH MESH 08307644-45 - Piet Hinoul_s email and Excel attachment with 104 RCTs attached to email
ETH MESH 09268043-45
ETH.MESH. 00484929 - 2007 & 2008 Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH..07462313 - Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response
ETH.MESH.00000172 - 8/25/11 Email from Marie Hobson to Kevin Frost attaching registration list for call
ETH.MESH.00000173 - 8/25/11 Registration list for 8/25/11 call
ETH.MESH.00001595-1606 - Reisenauer, C. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. Eur J Obst Gynecol Reprod Biol 2006
ETH.MESH.00003895 - Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee
ETH.MESH.00012009-089 - Clinical Study Report: Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse.
ETH.MESH.00012009-74 - Cosson, M. Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse(French 1 year CSR)
ETH.MESH.00012090-163 - Robinson, D. Clinical assessment of the TVM technique for treatment of genital prolapse. Final Report of 12-month evaluation. (US 1 year CSR)
ETH.MESH.00013529-534 - Prolift+M IFU
ETH.MESH.00016032-039 - Kohli, N. Augmenting pelvic floor repairs. 2006 Supplement to OBG Management
ETH.MESH.00017362-368 - Elmer C, et al. Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery, J Urol (2009), 181 (3), 1189-95.
ETH.MESH.00017553-560 - Tunuguntla, H. Female Sexual Dysfunction Following Vaginal Surgery: A Review. Journal of Urology 2006; 175: 439-446
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00019117-21 - Letter from Scott H. Jones to Price St. Hilaire re: Prosima US Launch Plan; cc: Renee Selman, et al.
ETH.MESH.00020763 - Prolift +M Profession Education Slide Deck
ETH.MESH.00020764 - Prolift +M Profession Education Slide Deck

**Production Materials**

ETH.MESH.00031323 - Memo to Customer from Sean M. O'Bryan dated 2.8.05 regarding Gynecare Prolift
ETH.MESH.00031324-25 - Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair
ETH.MESH.00064002-04 - Email string, top one from Judith Gauld to Scott Jones re: US preceptors for Prosima.
ETH.MESH.00064054 - Gynecare Prosima ™ Pelvic Floor Repair System - Global Launch Strategy
ETH.MESH.00064138-39 - Document entitled "PROSIMA Critical Success Factors."
ETH.MESH.00071755 - Prosima - Apical Support Learning Guide
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00076167 - Letter from Bryan Lisa to Dan Smith re: Prosima Product Release Authorization; cc: Stephanie Kute, Jennifer Paine.
ETH.MESH.00076710-90 - Clinical Study Report. Evaluation of Prosima for Pelvic Organ Prolapse. Protocol Number: 300-06-005. "A Prospective, Multi-centre Study to Evaluate the Clinical Performance of Gynecare Prosima Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse."
ETH.MESH.00077073-093
ETH.MESH.00077094-111
ETH.MESH.00077395
ETH.MESH.00077739 - Prosima Story
ETH.MESH.00078114-15 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.00081288-89 - Memo to Jennifer Paine, et al from Renee Selman dated 1.16.08 regarding Project Lightning Status
ETH.MESH.00082651-54 - Email string, top one from Marcus Carey to J. Meek, D. Robinson, P. Hinoul,et al. re: Technical feedback on Prosima.
ETH.MESH.00083812-3814
ETH.MESH.00086463-65 - E-mail from Piet Hinoul to Zeb Viana, et al. regarding TR: PROSIMA TAKE AWAY MESSAGES; cc: Bart Pattyson, et al.
ETH.MESH.00093526-44 - Prolift +M Profession Education Slide Deck
ETH.MESH.00093991 - Prolift +M Profession Education Slide Deck
ETH.MESH.00108120-21 - Email string, top one from Douglas Grier to Lissette Caro-Rosado, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson.
ETH.MESH.00125373 - Email string, top one from Tom Eagan to Erin Haggerty re: Dr. Sepulveda.
ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on Prolift+M for input
ETH.MESH.00127103 - Email from Greg prine to Scott Jones, Jonathan Meek re: Prosima Road Show; cc: Lesley Fronio and Kevin Mahar.
ETH.MESH.00127125-26 - Email From Lewis to Mahar, et al. re: How did Dr. Grier's Prosima cases go?
ETH.MESH.00129102 - Suggested Remarks - Incontinence and Pelvic Floor Summit What a Difference a Decade Makes
ETH.MESH.0013114-51 - Email string, top one from Stephanie Grupe to Kevin Mahar re: Prosima Global Launch Team.
ETH.MESH.00144449 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).

**Production Materials**

ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104-10 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients e: Pre-Reading for Prolift+M: Internal Use Only. Not Copy Reviewed or For Distribution
ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.
ETH.MESH.00281482-84
ETH.MESH.00295355 - 2010 TVT Exact Prof Ed
ETH.MESH.00303310-13 - Memo from Dan Lamont to Gynecare Prosima Risk Management Report (RMR-0000029) re: Pelvic Floor Product(s) Complaint Review for Gyneacre Prosima Risk Management.
ETH.MESH.00308094 (2629_2006-07-12) - 2006 TTVT-Secur
ETH.MESH.00310205 - Product Quality Issue re: Prosima signed by Mark Yale.
ETH.MESH.00310206 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).
ETH.MESH.00316849-50
ETH.MESH.00318930 - (Draft) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00318934 - Document entitled " Delay in Prosima Activities."
ETH.MESH.00326911 - Ethicon Delayed Prosima Launch by Two Years
ETH.MESH.00329474-509 - Project Mint Design Review
ETH.MESH.00335084-85 - Email from Daniel Lamont to Sungyoon Rha, et al. re: Mint Functional Strategies.
ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on the Tension Free Vaginal Tape (TVT) System for Compliance to FDA G-95/ ISO 10993/ EN 30993
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device
ETH.MESH.00354732 - Gynecare TTVT Abbreviated Professional Education.
ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.00369995 - 2008 TVT Family of Products
ETH.MESH.00369999 (2008-135) - 2008 TTVT-Secur
ETH.MESH.00370315 - Prosima Training Deck 1
ETH.MESH.00370421 (TVTO_0113-09-8.11) - TTVT-O FDA Public Health Notice
ETH.MESH.00371595-903 - Prosima 510(k) and Clearance letter
ETH.MESH.00372564-68 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number 2003-016
ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)
ETH.MESH.00373310 - Gynecare TTVT Tension-Free Support for Incontinence: General Professional Education Deck.
ETH.MESH.00373310-88 - 2003 TTVT Support for Incontinence General Prof Ed Deck
ETH.MESH.00393045-46 - TTVT-O Procedural Steps
ETH.MESH.00394849 - Gynemesh PS Panel Powerpoint - Drs. Robinson, Miller, Winkler, England

## Production Materials

ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL, June 22, 2001
ETH.MESH.00397674 - 2002 Dr. Miklos Minimizing and Managing TTVT Complications
ETH.MESH.00405513-514
ETH.MESH.00409158 - (Official) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00418855-56 - Email string, top one from Andrew Meek to Jonathan Fernandez, et al. re: Prosima Preceptor Recommendation Form; cc: Kevin Frost, et al.
ETH.MESH.00424374-75 - Email string, top one from Jonathan Fernandez to Rhonda Peebles re: remaining 2010 labs; cc: Robert Zipfel.
ETH.MESH.00426441 - Email from Kevin Frost to Robert Zipfel, et al. re: Prosima 2-year slide deck; cc: Paul Parisi.
ETH.MESH.00442129 - PowerPoint Mechanical vs. "Machine"-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammerer
ETH.MESH.00455676-77 - Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima Jan 2007 update; cc: Bob Roda, et al.
ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force
ETH.MESH.00467320 - Email string, top one from Andrew Meek to Bart Pattyson, Paul Parisi re: November Lab.
ETH.MESH.00484929 - 2005-2006 Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.00495796-98 - Email string, top one from Jennifer Paradise to Melissa Doyle, et al. re: Prof Ed through Tele-Mentoring; cc: Paul Parisi, et al.
ETH.MESH.00510562-63 - Email string, top one from Kevin Frost to DL-ETHUSO EWHU DMs, et al. re: 1st Prosima Virtual Round Table Tomorrow; cc: Matt Henderson, et al.
ETH.MESH.00516424-27
ETH.MESH.00520649-722 - 2006 US TVM 12 Month Clinical Report
ETH.MESH.00523617 (2007-4144) - 2007 TTVT-Secur Critical Steps
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00541379-80 - Mesh Fraying for TTVT Devices
ETH.MESH.00541708-09 - Document entitled "Notes from Competitive Ad Board."
ETH.MESH.00541873 - Chart listing Proposed Lab Scheduling for August 4th.
ETH.MESH.00541876-78 - Email string, top one from Bart Pattyson to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.
ETH.MESH.00542347-48 - Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.
ETH.MESH.00542463 - Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: 2-Year Clinical Data
ETH.MESH.00547021 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.00547036-37 - Email string, top one from Bart Pattyson to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.
ETH.MESH.00547500-01 - Email re: 69% Success
ETH.MESH.00573815 - Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima* Pelvic Floor Repair System) June 2010.

## Production Materials

ETH.MESH.00573860-78 - (Draft) Sayer, T., et al. "Medium-term Clinical Outcomes Following Surgical Repair for Vaginal Prolapse with Tension-free Mesh and Vaginal Support Device."
ETH.MESH.00575257 - Abbrevo laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00575580-81 Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.
ETH.MESH.00575634-35 - ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."
ETH.MESH.00575818-820 - PX0198 - Piet email re Prolift
ETH.MESH.00578081-83 - Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.
ETH.MESH.00578550 - (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."
ETH.MESH.00579296 - Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolapse Patients.
ETH.MESH.00580588-89 - Email string dated 3/25/2010, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch
ETH.MESH.00580711-13 - Email re: Piet explains PS in Prosima
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00591563-65 - Email re: Smelly VSDs
ETH.MESH.00592224-29 - E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima
ETH.MESH.00592585-87 - Email re: No RCT for Prosima
ETH.MESH.00594266 - Email re: Overstating Success - Less Misleading
ETH.MESH.00594455 - Email re: Stop communicating over email
ETH.MESH.00594528 - Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commerical claims of 92.3% above the hymen.
ETH.MESH.00595468-70 - Goldman, H., FitzGerald, M. "Opposing Views: Transvaginal Mesh for Cystocele Repair," J Urol (2010) 183:430-432.
ETH.MESH.00595889-90 - Email string, top one from Kevin Frost to Aaron Kirkemo re: Prosima presentation; cc: Tom Affeld.
ETH.MESH.00604183-86 - Email string, top one from Piet Hinoul to Judi Gauld and Colin Urquhart re: PISQ, and score when unable to have sex.
ETH.MESH.00631782-84 - FDA Letter re: K063562 Gynecare Prosima
ETH.MESH.00637343 - 2004 ETHICON Product Development Process - Gynemesh PS
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00662233 - Email from Scott Jones to DL-Ethusso dated 12/15/2009 re: PAGS Leads
ETH.MESH.00679637-40 - Email string, top one from Zenobia Walji to Ron Naughton, et al. re: Prolene Soft Mesh '05 proposed pricing; cc: Kevin Maher, et al.
ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev.
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev. 2

**Production Materials**

ETH.MESH.00759327-35 - Document entitled "Experience what's new in incontinence and pelvic floor repair." 2010 ICS IUGA Executive Agenda
ETH.MESH.00776993-7000 - Prosima Sales Aid
ETH.MESH.00791497 - Email re Prosima Brochure and DVD
ETH.MESH.00800521-22 - Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.
ETH.MESH.00806974-75 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.00807570 - Revised Chart listing Proposed Lab Schedule
ETH.MESH.00807772-74 - Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.
ETH.MESH.00807972-73 - Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.00808121-22 - Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.
ETH.MESH.00817181 - Email dated 1/22/2010 from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.
ETH.MESH.00820634 - Invitation to participate in Gynecare Prosima Virtual Round Table
Eth.Mesh.00826114 - 2005 Dec 5 D. Robinson email regarding voiding and Prolift
ETH.MESH.00832749-54 - Risk Management Report: Prosima Pelvic Floor Repair Kit
ETH.MESH.00833948-49 - Email from David Robinson to Jessica Shen re: Prosima Study.
ETH.MESH.00834910-11 - Email string , top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.
ETH.MESH.00840886-87 - Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.
ETH.MESH.00843043 - Email from David Robinson to Jacqutin Bernard, Judith Gauld and Jonathan Meek re: cancellation of scheduled Prosima training.
ETH.MESH.00848020-21 - 2006 Jan 27 D. Robinson email regarding voiding and Prolift
ETH.MESH.00849014-17
ETH.MESH.00850335-36 - Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.
ETH.MESH.00851319-21 - E-mail string dated 1/21/2010, top one from Piet Hinoul to Clifford Volpe and David Robinson re: dimensions of the PROSIMA implant
ETH.MESH.00851319-321 - Email string, top one from P. Hinoul to C. Volpe, et al. re: Prosima implant dimensions.
ETH.MESH.00856579-82 - E-mail string dated 11/3/2010 re: neo clinical trial. Piet Hinoul: "Each individual study does not contribute to the success of those products
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00860239-310 - TVT-O IFU
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.

## Production Materials

ETH.MESH.00895089-91 - Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.
ETH.MESH.00916799 - Project MINT Charter Review
ETH.MESH.00921692-94 - Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.
ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement
ETH.MESH.00925065-67 - Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.
ETH.MESH.00991195-257 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number CT-TVM-001-03
ETH.MESH.00993273 - 2006 TTVT-O Summit Presentation by Raders and Luente
ETH.MESH.00993273 - TTVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.01075187-215 - Clinical Expert Report Gynecare Prolift Pelvic Floor Repair System dated 7.2.10
ETH.MESH.01128679-98 (TVTS007) - 2007 TTVT-Secur Procedural Steps
ETH.MESH.01136239-40 - Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.
ETH.MESH.01154031-37 - Clinical Expert Report - Gynemesh Prolene Soft
ETH.MESH.01198058 - (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."
ETH.MESH.01200286 - Powerpoint: Gynecare Prosima : Overview.
ETH.MESH.01201973 - Proposed Lab Schedule (2nd Revision)
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01212972 - Hinoul presentation Incontinence Overview
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01228079-84 - Nilsson Podcast Transcript
ETH.MESH.01237077-79 - Email dated 9/3/2009 from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01244824-26 - Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.
ETH.MESH.01261962 (2005-1819) - TTVT-O Summit by Raders, Rogers, Luente
ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009
ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.
ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling
ETH.MESH.01310817-29 - Ethicon Biocompatibility Risk Assessment for Gynecare Prolift Total Pelvice Floor Repair System dated 1.19.05
ETH.MESH.01317508-613 - TTVT Factbook DHF - Revised 05.14.2001
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ETH.MESH.01320351-67 - Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006
ETH.MESH.01411037-39 - Summary re: Project Mint
ETH.MESH.0141137-39 - Document re: summary of changes in mesh implant from Project Mint to final production.
ETH.MESH.01428106-112 - Carvigni, M. The use of synthetics in the treatment of pelvic organ prolapse. Curr Opin Urol 2001; 11: 429-435.
ETH.MESH.01593930-42 - Prosima Clinical Expert Report (not signed or dated).
ETH.MESH.01595614-753 - Prolift +M IFU
ETH.MESH.01612323-33 - Patient Brochure: Pelvic Organ Prolapse "Get the Facts, Be Informed, Make Your Best Decision."
ETH.MESH.01638150 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System Backrgound; Halina Zyczynski, M.D.
ETH.MESH.01678340 - Email from Andrew Meek to Melissa Doyle et al. re: Approved Prosima Receptors.
ETH.MESH.01707963 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.01708116-17 - Email string, top one from Bart Pattyson to Georgia Long re: TVT Abbrevio and Prosima training; cc: Elizabeth Kolb, Andrew Meek.
ETH.MESH.01708180 - Chart listing financial information re: preceptors.
ETH.MESH.01708190 - Chart listing financial information re: preceptors.
ETH.MESH.01730626-29 - Email string, top one from Dr. Antar to Bart Pattyson re: Prosima presentation.
ETH.MESH.01733531-535 - Kasturi, S. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203: 1.e1-1.e5
ETH.MESH.01752532-535 - Mesh design argumentation issues
ETH.MESH.01775482 - Prosima letter delying launch
ETH.MESH.01776504-10 - Email re: 60% Success
ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.
ETH.MESH.01782783-785 - (02.02.2006) Notes from meeting with Dr. V. Lucente and Dr. M. Murphy (Allentown, PA) to discuss Prolift RCT.
ETH.MESH.01784823-28 - Clinical Expert report-Laser Cut Mesh
ETH.MESH.01785259-260 - Email dated 1/17/2010 from Dr. Piet Hinoul to Dr. David Robinson, et al. Re: +M relaxation
ETH.MESH.01803816-18 - Summary re: Project Mint
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TTV mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01821586-87 - Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Dan Smith, et al.
ETH.MESH.01822361-363 - Dan Smith Email regarding TTV Secur October 18, 2006
ETH.MESH.01822361-62 - Dan Smith Email regarding TTV-Secur leading to less retention
ETH.MESH.02001398-404 - Gynecare Prolift IFU (English Only)
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ETH.MESH.02017152-158 - (02.23.2007) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.02020023-024 - Prosima ISO cytotoxicity biocompatibility
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02050884-909 - Prosima Key Procedural Steps
ETH.MESH.02059150-151 - May 24, 2006 Memo RE: First Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.02066770-71
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02092919-921 - Prosima Clinical Strategy
ETH.MESH.02105765-771 - FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence issued 10.20.08; Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence posted by FDA dated 10.23.08 at bottom; Information on Surgical Mesh for Hernia Repairs posted by FDA dated 10.23.08
ETH.MESH.02114615-16 - Email string, top one from Libby Lewis to Donna Abely, et al. re: Remaining 2010 labs.
ETH.MESH.02156379-80
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ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh.
ETH.MESH.02215374-375 - Jacquetin B. Prolene Soft (Gynecare) Mesh for Pelvic Organ Prolapse Surgical Treatment: A Prospective Study of 264 Patients. Abstract 767
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ETH.MESH.02219584 - Scion PA-SUI Treatment Unmet Needs Exploratory Research
ETH.MESH.02229013 - Email re: IFU errors
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ETH.MESH.02229054 - Video: "What to Expect"
ETH.MESH.02229055 - Video: "VSD Case Series 1"
ETH.MESH.02232685 - Marketing: "Your Proof: Her dance class."
ETH.MESH.02232773-801 - Prolift +M Profession Education Slide Deck
ETH.MESH.02232854-74 - Prolift +M Profession Education Slide Deck
ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion
ETH.MESH.02233126-187 - Prolift +M Profession Education Slide Deck
ETH.MESH.02233126-187 - Prolift+M Educational Module
ETH.MESH.02233290 - Prolift +M Profession Education Slide Deck
ETH.MESH.02233410 - US Launch - Premarket Preparation (PMP) 2009 US Sales Meeting Brief
ETH.MESH.02233417 - Prosima New Product Request Form
ETH.MESH.02233418-38 - Prosima - Surgical Technique
ETH.MESH.02233439-51 - US Training 1-year clinical data: A New Operation for Vaginal Prolapse Reapir Using Mesh and a Vaginal support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study.
ETH.MESH.02233452-67 - Prosima - US Training - Background and Development History
ETH.MESH.02233468-538 - Prosima Prof Ed (71 slides)
ETH.MESH.02233539 - Prosima - New Product Request Form
ETH.MESH.02233540 - Prosima - 2009 Sales Training Program

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ETH.MESH.02233605 - (B&W) Webinar Invite "The treatment of Symptomstiv Moderate Pelvic Organ Prolapse."
ETH.MESH.02233640 - (B&W) Prosima - Module 4: 2-Year Clinical Data
ETH.MESH.02233651-73 - One year Clinical Outcomes Following Prolapse Surgery with Non-Anchored Mesh and a Vaginal Support Device. Results from the International Multicenter Gynecare Prosima™ Study.
ETH.MESH.02233674-92 - (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?"
ETH.MESH.02233699-710 - Prosima - An Interview with Dr. Marcus P. Carey.
ETH.MESH.02233713 - Objective Success Rate Learning Guide
ETH.MESH.02233726-27 - Prosima Product Page on Ethicon-360 12.09
ETH.MESH.02233728 - (native) Gynecare Prosima™ Key Procedural Steps
ETH.MESH.02233751-833 - Prosima Prof Ed 2 (83 slides)
ETH.MESH.02233834 - (B&W) 2009 Sales Aid Guide
ETH.MESH.02233840 - MRI Flashcard "Prosima - The first fixationless mesh system that maintains anatomical position."
ETH.MESH.02233842 - Virtual Round Table Registration Form 9.2010
ETH.MESH.02233843-49 - Clinical Study Findings Discussion for Gynecare Prosima™ by Piet Hinoul (Audio Transcript).
ETH.MESH.02233851-51 - Document entitled "PROS-438-10-9/12 Prosima Short Procedural Video."
ETH.MESH.02233857-59 - AJOG Press Release (Draft)
ETH.MESH.02233862-80 - AALG in booth presentation. "Proof in the Treatment of Pelvic Organ Prolapse" Douglas Van Drie, M.D.
ETH.MESH.02233881-88 - Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.
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ETH.MESH.02233963 - Virtual Round Table Invitation 9.2010
ETH.MESH.02233964 - (B&W) Prosima DVD
ETH.MESH.02234001-02 - (Marketing) The Gynecare Prosima™ Pelvic Floor Repair System Story
ETH.MESH.02234005-171 - Prosima Sales Training Program
ETH.MESH.02234173-77 - Prosima Messgaging practice Coaching Check List
ETH.MESH.02234195-196 - Prosima Workshop Takeaway
ETH.MESH.02237107-15 Introducing Gynecare Prosima for Ethicon Epiphany 247.
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both
ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.
ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.
ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.
ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU
ETH.MESH.02293981 - Email from Adrian Roji dated 7/19/11 re Approved FDA Notification Response
ETH.MESH.02318553-54 - Gynecare Prosima™ Combined Pelvic Floor Repair System Clinical Strategy.

**Production Materials**

ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02322037-39 - Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial.
ETH.MESH.02330766 - TVT-O (Reproducible Vaginal Approach) (TVTO-384-10-8-12)Production 36_000124_4580875_d
ETH.MESH.02330767 - Marketing Materials for Prosimma
ETH.MESH.02340306-69 - TVT IFU
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ETH.MESH.02340471-503 - TVT IFU
ETH.MESH.02340504-67 - TVT IFU
ETH.MESH.02340568-90 - TVT-S IFU
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ETH.MESH.02341203-13 - TVT Abbrevo IFU
ETH.MESH.02341398-410 - Prosimma IFU (6.18.10 to discontinuance) - English only 13 pages
ETH.MESH.02341398-453 - Prosimma IFU
ETH.MESH.02341398-453 - Prosimma IFU
ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341454-521 - Prolift IFU
ETH.MESH.02341522-527 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341522-89 - Prolift IFU
ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341658-733 - Prolift IFU
ETH.MESH.02341734-809 - Prolift 2009-2010 IFU
ETH.MESH.02342097 Prolene Soft IFU
ETH.MESH.02342101 Prolene Soft IFU
ETH.MESH.02342102 Prolene Mesh IFU
ETH.MESH.02342152-54 Prolene Mesh IFU
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02579701-06 - Email re: Piet re Problem with posterior inserter
ETH.MESH.02596085 - Letters to the Editor 2010; 1457
ETH.MESH.02597949-50 - Hinoul, P., et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine."
ETH.MESH.02599918-20 - Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosimma Data Conference Call.
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02614610-624 - Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BF-2004-1920) Version 2
ETH.MESH.02615519-658 - Prolift +M IFU

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ETH.MESH.02616825-27 Prolene Soft IFU
ETH.MESH.02658316 - Cover Letter
ETH.MESH.02658317-352 - Postmarket Surveillance Study No. PS120043; Gynecare Prolift +M Pelvic Floor Repair Systems; Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.02967410-12 - Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.
ETH.MESH.03048942 - Document entitled "New" Mint January 05, 2006.
ETH.MESH.03049774-75 - Gynecare Prosima* Combined Pelvic Floor Repair System: Clinical Strategy.
ETH.MESH.03056578-80 - Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima* investigator bulletin.
ETH.MESH.03086214-219
ETH.MESH.03109341 - Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.
ETH.MESH.03160821 - Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.
ETH.MESH.03160822-23 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.03160827-28 - Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.
ETH.MESH.03162936-38 - Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.
ETH.MESH.03378923-933 - Prosima Patient Brochure - Stop Coping Start Living
ETH.MESH.03393725-31 - Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract
ETH.MESH.03396246 - VSD Patient Information (Slim Jim) - "Stop Coping Start Living."
ETH.MESH.03427757-59 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.
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ETH.MESH.03440816-36 - Prosima Revised Webinar Deck - Overview
ETH.MESH.03458123-38 - TTV Patient Brochure
ETH.MESH.03459088-104 - Patient Brochure
ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007
ETH.MESH.03466382-83 - Email string dated 5/12/2011, top one from Kevin Frost to Benjamin Bouterie re: Dr. Bedestani; cc: Stacy Hoffman
ETH.MESH.03471308 - Chart entitled "Pedm Monthly Status."
ETH.MESH.03612364 - Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.
ETH.MESH.03626267-69 - Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.
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ETH.MESH.0370392 (3914_2007-08-22) - 2007 TVT-Secur
ETH.MESH.03715787-793 - Gynemesh PS CER (2002) - Weisberg
ETH.MESH.03715978 - Weisberg email re: TTV question.
ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03736120-27 - Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03751819 - 2009 The Science of What's Left Behind
ETH.MESH.03895925-26 - Email from Frost to Affeld, et al. re: Sales Rep Training on Prosima 5/18
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03905968-975 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905992-6000 - Patient Brochure
ETH.MESH.03906001-020 - Prolift +M Patient Brochure
ETH.MESH.03906001-20 - Patient Brochure: What You Should Know About Pelvic Organ Prolapse. Stop Coping. Start Living. Dated 11/9/2009
ETH.MESH.03906001-20 - Prosima Brochure
ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living
ETH.MESH.03906037-52 - Patient Brochure
ETH.MESH.03907468-9 - Second Generation TTV - by Axel Arnaud
ETH.MESH.03910175 - Email string re - Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TTV - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03911901-910 - Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006)
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TTV TTV-O
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ETH.MESH.03941623 - DeLeval Email RE: TTV ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results
ETH.MESH.03962244 - Dear Surgeon letter 7/18/11

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ETH.MESH.03989722-23 Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.
ETH.MESH.03989781-82 - Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.
ETH.MESH.03991591-92 - Memo re: Gynecare Studies; created by Randall Gore.
ETH.MESH.04005090-91 - Ethicon informs FDA of discontinuation
ETH.MESH.04005092-93 - Ethicon's Notification to FDA to Decommercialize
ETH.MESH.04005095-96 - Ethicon's Notification to FDA regarding Decommercialization
ETH.MESH.04042511-12 - Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."
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ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04077172 - Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010
ETH.MESH.04079609 - Gynecare TTV Abbrevio Professional Education (Dr. Babcock).
ETH.MESH.04081189 - Meeting Agenda
ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868 - Email re : 10100080654 and TTV IFUs
ETH.MESH.04181761-762 - Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile
ETH.MESH.04201880 - Prosima Training Deck 2
ETH.MESH.04202101 (2008-448)
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ETH.MESH.04381806-19 - Literature Review on Biocompatibility of Prolene Sutures and Impants
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ETH.MESH.04474731 - Ethicon's Cover Letter Response to TTV Secur 522 Order
ETH.MESH.04474733 - Ethicon's TTV Secur Postmarket Surveillance Study Plan: {S120095; Gynecare TTV Securm System
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ETH.MESH.04476274-75 - Email re: Meeting Minutes from April 18 2012 meeting w FDA
ETH.MESH.04543334 - Email re: Faculty & Customer Call Post-FDA Panel Mtg on 9/12
ETH.MESH.04543335 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04543335 - Powerpoint "Pelvic Organ Prolapse Surgical Mesh Discussion"
ETH.MESH.04543336 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04548931-35
ETH.MESH.04548975 - Email re: Piet's response to 522 FDA refusal clean
ETH.MESH.04550996-97 - Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD.
ETH.MESH.04551757-795 - E-mail with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM
ETH.MESH.04551946 - Ethicon Gynecare WW Commercialization Decision - US Surgeon Letter 6/1/12
ETH.MESH.04554662 - Ethicon Gynecare WW Commercialization Decision - US Frequently Asked Questions 6/1/12
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ETH.MESH.04556236 - Email re: Piet's takeaways from 2011 FDA meeting
ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010;116:293-303

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ETH.MESH.04567674 - Ethicon Gynecare US Commercialization Decision - Core Messages 5/15/12
ETH.MESH.04567677-79 - Frequently asked questions 5/15/12
ETH.MESH.04567680-81 - Message from Laura Angelini to Internal WW Associates 5/15/12
ETH.MESH.04567686-79 - US Sales Call Script for Matt Henderson 5/15/12
ETH.MESH.04567695 - Ethicon Gynecare WW Commercialization Decision - Core Messages 6/1/12
ETH.MESH.04567698 - Ethicon Gynecare WW Commercialization Decision - Standby Statement 6/1/12
ETH.MESH.04567707 - Ethicon Gynecare WW Commercialization Decision - Chuck Austin Message to WW General Surgery Employees 6/1/12
ETH.MESH.04567726 - Ethicon Gynecare WW Commercialization Decision - Tim Schmid message to US General Surgery Employees 6/1/12
ETH.MESH.04568448 - Email re: Piet following 2011 Ad Com
ETH.MESH.04568519 - Email dated 6/8/2012 from Matt Henderson to Tim Schmid re: 522 Communication Recap
ETH.MESH.04568717-718 - Email from Tim Schmid to Chuck Austin dated 6/8/12 re: Prolift +M withdrawal notice
ETH.MESH.04925426 - DX10341 Beath email to Kanerviko
ETH.MESH.04925553-91 - Postmarket Surveillance Study PS120044, Gynecare Prosima™ Pelvic Floor Systems - K063562 dated 2/1/2012
ETH.MESH.04926150-151 - DX24802 - Piet discussing 522 order
ETH.MESH.04926191-92
ETH.MESH.04927339-40 - FDA's Response to Discontinuation Notification-07.09.2012
ETH.MESH.04931596 - Kanerviko email re 40000 page response to 522
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevio
ETH.MESH.04939001 - Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.04984220-221 - DX24790 - Lucente email
ETH.MESH.05009194
ETH.MESH.05092843 - Chart listing lab schedule for August 11th.
ETH.MESH.05106233-34 - Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder: Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.
ETH.MESH.05164225-26 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.05165675-77 - EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.
ETH.MESH.05217098-100 - FDA Clearance Letter, Modified PROLENE
ETH.MESH.05217103-44 - Letter to FDA re: Notification of Intent
ETH.MESH.05222673-705 - TVT IFU
ETH.MESH.05222686-88 - TVT IFU (4th version) 4.7.06-10.7.08
ETH.MESH.05225354-85 - TVT IFU

## Production Materials

ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05320909 (2008-135)(38 slides summit) - 2008 TVT-Secur
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05343480-82 - Email string, top one from Joseph Lanza to Bart Pattyson re: Review EWHU IUGA events.
ETH.MESH.05343757-58 - Email string, top one from Kevin Frost to Bart Pattyson re: July 31 Heads Up; cc: Lissette Caro-Rosado.
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05469908-12 - Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05571741 - Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed - Approved: Request for Speaker Event.
ETH.MESH.05573916-17 - Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.
ETH.MESH.05588123-126 - Stephen Wohlert Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05741094 - Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.
ETH.MESH.05741890-91 - Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.
ETH.MESH.05795421-508 - 2001 slides from Parisi binder
ETH.MESH.05795537-99 - 1998 TVT Slide Deck
ETH.MESH.05799233-239 - TVT Exact IFU
ETH.MESH.05799233-316 - TVT-E IFU
ETH.MESH.05820723 - Dear Surgeon Letter re Discontinuation
ETH.MESH.05835298-308 - Pelvic Organ Prolapse - Patient Counseling Guide.
ETH.MESH.05837063-110 - Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.
ETH.MESH.05837242 - DX23938 - Letter re FDA 2011 Notice
ETH.MESH.05840629 - Powerpoint Presentation entitled "Continuum of Education."
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05922038 - Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.
ETH.MESH.05947160-63 - Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up_Gynecare_Reminder; cc: Fernando Nassif, et al.
ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05967586-87 - Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.
ETH.MESH.05987605-06 - Email re: Piet's response to 522 FDA refusal
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06049894-96 - FDA posting FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse issued 7.13.11
ETH.MESH.06087471-72 - TVT Patient Brochure
ETH.MESH.06087513-14 - Patient Brochure

**Production Materials**

ETH.MESH.06113091-92 - Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.
ETH.MESH.06124656-57 - Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.
ETH.MESH.06124954-55 - Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.
ETH.MESH.06125000-01 - Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.
ETH.MESH.06125058 - Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.
ETH.MESH.06125098 - Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.
ETH.MESH.06125277 - Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.
ETH.MESH.06125309 - Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.
ETH.MESH.06125502 - Email string, top one from Georgia Long to Bart Pattyson re: may 8th.
ETH.MESH.06151466-67 - Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.
ETH.MESH.06238611 - Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.
ETH.MESH.06255523-34 - Gynecare Prosima Pelvic Floor Repair System: An expert interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the inventor of the Gynecare Prosima system
ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361
ETH.MESH.06388151 - Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints
ETH.MESH.06480608-09 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.06482821-22 Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.
ETH.MESH.06585815 - Powerpoint: Agenda
ETH.MESH.06591558-59 - Email string, top one from Tom Affeld to Shwetal Narvekar re: Pre-launch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06769156 - Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval.
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-71 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.07105727 - Email string, top one from Laura Vellucci to Colin Urquhart re: Prosima publication.

## Production Materials

ETH.MESH.07189091 - Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.
ETH.MESH.07190144-45 - Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07201006 - Prolift Professional Education Slide Deck (2007)
ETH.MESH.07219196-209 - Clinical Expert Report - Prosima™ signed by David Robinson.
ETH.MESH.07226579-590 - 2000 - TTV CER
ETH.MESH.07229215-45 - Clinical Expert Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.07229312-42 - Clinical Expert Report Gynecare Prosima™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012
ETH.MESH.07246690-719 - Study Report dated May 8, 2012: A systematic review of patient-years of experience in prospective randomized controlled trials (RCTs) in incontinence.
ETH.MESH.07296496 - Chart listing Week Schedule and Lab Flow.
ETH.MESH.07308636-37 - Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc: Lissette Caro-Rosado, et al.
ETH.MESH.07324554-555
ETH.MESH.07351297 - Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>
ETH.MESH.07374762-63 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.07379573-74 Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07384790-91 - Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.07587090-91 - Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.
ETH.MESH.07628243 - EWH&U Gynecare Prosima™ Pelvic Floor Repair System Faculty Checklist.
ETH.MESH.07630654 - Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.
ETH.MESH.07631488 - Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.
ETH.MESH.07631752-53 - Email string, top one from Eric Globerman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.
ETH.MESH.07631967-68 - Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.
ETH.MESH.07632042 - Event request form for Sepulveda Preceptorship.
ETH.MESH.07632042-43 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.07636090 - Prosima Cadaver Lab Invitation
ETH.MESH.07653362-63 - Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.07931680-81 - Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.

## Production Materials

ETH.MESH.07951163 - Document re: Prosima's apical/anatomical success rates and functional outcomes.
ETH.MESH.07953429-33 - EWH&U 2011 Field Visit Letter
ETH.MESH.07977911
ETH.MESH.08003181-96 - TTV Patient Brochure
ETH.MESH.08003231-46 - TTV Patient Brochure
ETH.MESH.08003247-62 - Patient Brochure
ETH.MESH.08003263-78 - Patient Brochure
ETH.MESH.08003279-94 - TTV Patient Brochure
ETH.MESH.08003295-302 - TTV Patient Brochure
ETH.MESH.08021804-07 - Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.
ETH.MESH.08023741-44 - Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.
ETH.MESH.08033153 - Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Luber, Charles W. Nager, Emily S. Lukacz.
ETH.MESH.08048738-40 - Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.
ETH.MESH.08066452
ETH.MESH.08107354 - Gynecare TTV Tension-free Support for Incontinence: Professional Education Slides
ETH.MESH.08117473 - 2012 TTV-Exact Updated Prof Ed Slide Deck w Production Cover
ETH.MESH.08117625-26 - Prolift +M Profession Education Slide Deck
ETH.MESH.08135444 - Gynecare Prosima - Pelvic Floor Repair System Proctorship
ETH.MESH.08139049-118 - Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.
ETH.MESH.08156958 - 2002 TTV Advanced Users Forum Presentation
ETH.MESH.08161765 - Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.
ETH.MESH.08169582-620 - Surgical Practice of POP survey on Survey Monkey.
ETH.MESH.08290691
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08307644-45 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).
ETH.MESH.08309057-92 - Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."
ETH.MESH.08315779-810 - Clinical Expert Report Gynecare Prolift +M™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012
ETH.MESH.08328772-922 - Prosima - Patient Brochure Literature
ETH.MESH.08334244-45 - Email string re-Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.08375158-59 - Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TTV Abbrevio, Prosima, TTV Exact.
ETH.MESH.08384247
ETH.MESH.08384270 - Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garris.

## Production Materials

ETH.MESH.08421628 - Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12
ETH.MESH.08476311 - Cytotoxicity assessment of Ulstem sling
ETH.MESH.08492824 - Strategic Business Team Meeting - Meeting Notes
ETH.MESH.08565137-41
ETH.MESH.08640676 - Jones email 4/04/08 re Prosima update for RBDs
ETH.MESH.08791917
ETH.MESH.08945734-35 - ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."
ETH.MESH.08945742-44 - Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.
ETH.MESH.08945836-40 - Document entitled "Gynecare Prosima Claims List."
ETH.MESH.08948364-65 - Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.
ETH.MESH.08951725-26 - Email string, top one from Tom Affeld to Kevin Frost re: Prosima 2 year summary for eClinical Compendium.
ETH.MESH.08961175-76
ETH.MESH.08962682-83 - Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.
ETH.MESH.08962684-85 - Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.
ETH.MESH.08971152-53 - Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.
ETH.MESH.08971269-70 - Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.
ETH.MESH.08971271-72 - Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.
ETH.MESH.08971309-14 - Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.
ETH.MESH.08988155 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.
ETH.MESH.08988298-417 - EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.
ETH.MESH.09050450 - Memorandum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).
ETH.MESH.09100506 - Prolift Professional Education Slide Deck (2005)
ETH.MESH.09128451 - Chart entitled "Faculty Training."
ETH.MESH.09128545 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11
ETH.MESH.09138054-55 - Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinos, M.D.
ETH.MESH.09142383-84 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.09142511 - (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.
ETH.MESH.09144349 - Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.

**Production Materials**

ETH.MESH.09191424-26 - Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosima - Urgent; cc: Irene Leslie, Rosangela Ribeiro.
ETH.MESH.09207059 - Chart entitled "Grier."
ETH.MESH.09218452-53 - Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09283030 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283031 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283032 - Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283033 - Spreadsheet re: Budget Summary
ETH.MESH.09283034 - Spreadsheet re: Integrated Marketing
ETH.MESH.09283035 - Spreadsheet re: Summary
ETH.MESH.09283036 - Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283037 - Spreadsheet re: Budget Summary
ETH.MESH.09283038 - Spreadsheet re: Integrated Marketing
ETH.MESH.09290755 - Spreadsheet re: Q1 2012 Open PO Summary
ETH.MESH.09290760 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09290767 - Spreadsheet re: Uterine Health
ETH.MESH.09290769 - Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary
ETH.MESH.09290772 - Spreadsheet re: Budget Summary
ETH.MESH.09300480 - Spreadsheet re: Prosima All Day
ETH.MESH.09625725-29 - Government Submissions Log Sheet
ETH.MESH.09625731-37 - FDA Letter. re: approved drug application for polypropylene suture.
ETH.MESH.09625816 - FDA letter re: receipt of drug application for polypropylene suture.
ETH.MESH.09625817 - Letter to FDA re: new drug application for Polypropylene Suture.
ETH.MESH.09629447-48 - FDA Labeling Approval for Prolene
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09630649 - FDA Letter re: package insert for Prolene.
ETH.MESH.09634081 - Sections 6 re: adverse effects.
ETH.MESH.09634299-303 - FDA Letter re: approval of PMA supplement.
ETH.MESH.09634318 - Prolene Package Insert.
ETH.MESH.09634662-63 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09634664-88 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744840-45 - Patient Brochure
ETH.MESH.09744848-55 - Patient Brochure
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study
ETH.MESH.09922570-578 - TVTO PA (TOPA) R&D Memorandum of PA Mesh Assessments for TVTO-PA Katrin Elbert Dec.Revision 1
ETH.MESH.10027307-28 - TVT Surgeons Resource Monograph - June 2000

## Production Materials

ETH.MESH.10048035-36 - Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.
ETH.MESH.10179518-636 - Clinical Evaluation Report - Gynecare Gynemesh™ PS Nonabsorbable Prolene™ Soft Mesh signed by Piet Hinoul on 04.26.2013
ETH.MESH.10220659 - Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician
ETH.MESH.10224077 - Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.
ETH.MESH.10232708 - Email from Stevan Barendse to Greg Prine re: Prosima targets.
ETH.MESH.10281860 - 2013 Clinical Expertise TVT Prof Ed Slide Deck
ETH.MESH.10281860 - Tension-Free Midurethral Sling: Market Update.
ETH.MESH.10376963
ETH.MESH.10378001-02
ETH.MESH.10384309-310
ETH.MESH.10399553 - Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.
ETH.MESH.10608341-57 - Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima.
ETH.MESH.10686760-771 - Gynemesh PS aFMEA 2013
ETH.MESH.10686833-852 - Risk Management Report (RMR) for Gynemesh PS 2013
ETH.MESH.10817931 Pelvic Mesh Post-Market Surveillance Orders April 2012
ETH.MESH.10960414 - Email from Christopher O'Hara to Francois Barbe, et al. re: VRT for Prosima.
ETH.MESH.11048537-38 - Prosima E-blast No. 1 "The Proof of Success."
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report
ETH.MESH.11448841 - Conference Participant Report 8/25/11
ETH.MESH.11518663-65 - Email string, top one from Melissa Doyle to Arthur Mourtzinos re: Agenda for tomorrow's lab.
ETH.MESH.11522550-51 - Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.
ETH.MESH.11523079 - Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.
ETH.MESH.11524125-28 - Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.
ETH.MESH.11536046 - Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.
ETH.MESH.11538048-49 - Email from Frost to Globerman, et al. re: prosima usage northeast
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.11543719 - Robinson Gynemesh PS Presentation Awareness Module 4.7.04
ETH.MESH.11905619 - Spreadsheet: Prosima Virtual Roundtable Calls & Targets
ETH.MESH.1210987-95 - Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal
ETH.MESH.1222075-79 - Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12897617-78 - 2013 Clinical Evaluation Report - Prosima™ signed by Piet Hinoul.

## Production Materials

ETH.MESH.13314554 - Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.
ETH.MESH.13532200 - Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12
ETH.MESH.13577809-810 - Prosima Virtual RoundTable
ETH.MESH.13582263 - Reisenauer Prosima study
ETH.MESH.13589382 - Prosima Sales Aid 2
ETH.MESH.13589382 - Prosima Sales Aid 3
ETH.MESH.13589382 - Prosima Selling Guide
ETH.MESH.13592561 - Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"
ETH.MESH.13596052 - Prosima Sales Aid 4 (Proof)
ETH.MESH.13600015 - Barber Study - Defining Success After Surgery for POP
ETH.MESH.13618003-04 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.13618029-31 - EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."
ETH.MESH.13622000-70 - Prosima Trainee Deck Distribution
ETH.MESH.13626471 - Prosima Sales Aid 7 (Proof of Success)
ETH.MESH.13627691 - Expert interview with Dr. Carey (clean)
ETH.MESH.13635675 - 2011 B&W POP & SUI Patient Counseling Guide production copy
ETH.MESH.1363575.NATIVE
ETH.MESH.13637531 - Prosima presentation background and development history
ETH.MESH.13645631 - DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.
ETH.MESH.13649510 - Prosima Sales Training Program
ETH.MESH.13650207 - Prosima Sales Aid Brochure (Dance)
ETH.MESH.13670432 - Prosima Key Procedural Steps (double-sided)
ETH.MESH.13697383 - Prosima legal manufacturer Ethicon Sarl
ETH.MESH.13698543 - Prosima Marketing Material Roll-Out Letter.
ETH.MESH.13698840-59 - Bart Pattison editorial re prof ed bulletin
ETH.MESH.13699623 - Prosima sales training points
ETH.MESH.13699656 - Prosima DVD
ETH.MESH.13699656 - Prosima Sales Rep materials
ETH.MESH.13699656 - Prosima video with Van Drie and Grier.wmv"
ETH.MESH.13699674 - Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.
ETH.MESH.13713001 - Good image of Prosima box
ETH.MESH.13718001 - Prosima Objective Success Learning Guide
ETH.MESH.13718497 - Prosima Patient Brochure 2
ETH.MESH.13724290 - Prosima Apical Support Learning Guide
ETH.MESH.13726909 - Prosima Key Points
ETH.MESH.13727241 - Prosima Overview Presentation
ETH.MESH.13733674 - Prosima MRI Image and Sales Aid

## Production Materials

ETH.MESH.13756212-18 - Clinical study Finding Discussion for Gynecare Prosima™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).
ETH.MESH.13756219 - Gynecare Prosima™ Pelvic Floor Repair System MRI Address
ETH.MESH.13756384 - Prosima Virtual Round Table Trainee Confirmation
ETH.MESH.13756409 - Prosima Virtual Round Table Preceptor Follow-up and Invitation.
ETH.MESH.13756416-17 - Prosima Virtual Round Table Preceptor Confirmation.
ETH.MESH.13869166 - Powerpoint: Mint Project - Pelvic Floor Repair.
ETH.MESH.14427453-55 - FDA Clearance Letter re: K063562 Gynecare Prosima™
ETH.MESH.14427459-43 - Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.
ETH.MESH.14427562-63 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.14427564-65 - FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)
ETH.MESH.14427567-69 - Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.
ETH.MESH.14427578-61 - Traditionsl 510(k) Premarket Notification Gynecare Prosima™ Pelvic Floor Repair System.
ETH.MESH.15958178-82 - Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQS and Customer Letter.
ETH.MESH.161953-54 - 10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture Gynecare TVT Obturator System Sales Materials
ETH.MESH.16259973 - Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports
ETH.MESH.16350627-28 - Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.
ETH.MESH.16352932-34 - Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.
ETH.MESH.1751069-94 - 09/07/2009 Safety review: TVT and TTV-O procedures
ETH.MESH.17669942 - Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.17748760-61 - E-mail 4.25.11 from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.1784779-82 - Memo re: TTV-Base & TTV-O Complaint Review for Laser Cut Mesh (LCM) RiskAnalysis
ETH.MESH.1784823-28 - Clinical Expert Report
ETH.MESH.1809056-58 - Email re: Important Laser cut mesh update
ETH.MESH.1809080-81 - Memo re: Comparison of Laser-cut and machine-cut TTV Mesh to Meshes from Competetive Devices (BE02004-1641)
ETH.MESH.1815660-64 - Project Mulberry, Preliminary Clinical Diligence Report
ETH.MESH.18844812 - Jan 2007 email re delaying launch
ETH.MESH.18844812- Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse.
ETH.MESH.19308264-65 - Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.
ETH.MESH.19310234-38 - Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TTV-O
ETH.MESH.222852-863 - 12/15/2003, Gynecare Final Report # 03*0740, TTV Obturator System
ETH.MESH.222899-909 - Clinical Expert Report
ETH.MESH.2236604-609 - TTV Obturator Brochure; "Results, Precision & Proven Mesh"

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ETH.MESH.223779-84 - Risk Management Report, TTV Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3
ETH.MESH.22625140-45 - MDD CAPA # CAPA-003474
ETH.MESH.22631022-2029 - TTV - Response to Section 39 Request, D-1, 1-1002
ETH.MESH.22937156 - Email from Dan Smith re: NG TTV-O NDP - Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny
ETH.MESH.2340504-33 - TTV IFU
ETH.MESH.2340902-08 - TTV O IFU
ETH.MESH.262089-123 - Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out
ETH.MESH.3364663-66 - Email from O'Bryan re: ifu
ETH.MESH.3365250-251 - Email from Weisberg re: IFU update
ETH.MESH.341006-11 - 11/11/10 Letter from John Young re: Global Regulatory Strategy for TTV IFU (RMCP15506/E) Update (Part II, RA0001-2010, Rev. 1)
ETH.MESH.3427878-83 - TTV IFU
ETH.MESH.371496-594 - 01/28/98 Letter from FDA re: K974098 TTV System
ETH.MESH.3911390-1 - Email from Arnaud re: Transient Leg Pain with Mulberry
ETH.MESH.3922926-28 - Email re: OR Agenda Tunn
ETH.MESH.3932909-11 - History of TTV-O
ETH.MESH.3934952-67 - Tension-Free Vaginal Obturator Tape (TVOT) - April 30, 2003 - Meeting Report
ETH.MESH.4048515-20 - KOL Interview
ETH.MESH.4384126-65 - Clinical Evaluation Report, Gynecare TTV Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide
ETH.MESH.442825-26 - Email re: TTV Laser Mesh info
ETH.MESH.524746-48 - Email re: TTV Meeting with Agency
ETH.MESH.525573 - Email re: TTV Laser Cut Mesh
ETH.MESH.5315252-65 - Final Report, PSE Accession No. 97-0197, Project No. 16672
ETH.MESH.658177-98 - TTV Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting
ETH.MESH.6696411-19 - Email re: Performance Evaluation of TTV Prolene Blue Mesh
ETH.MESH.6859834-35 - Email re: Laser Cut TTV
ETH.MESH.6878438-39 - Memo re: VOC on new Laser Cut TTV Mesh
ETH.MESH.6882641-642 - Email from O'Bryan re: GYNECARE TTV Obturator System - FDA
ETH.MESH.6886410-11 - Email from Weisberg re: Mulberry
ETH.MESH.7393700 - 05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TTV PhysicianTraining Policy
ETH.MESH.7692905-07 - Email re: Mesh Fraying Dr. EBERHARD letter
ETH.MESH.8003295-301 - Patient Brochure: "Stop coping, start living."
ETH.MESH.8003303-17 - Patient Brochure: "Stop coping, start living."
ETH.MESH.823793-806 - Transobturator Vaginal Tape Inside-Out (TTV-O): From Development to Clinical Experience
ETH.MESH.865069-72 - Email from Dan Smith re: Draft report translated by "Babel fish" <a href="http://babelfish.altavista.com/tr">http://babelfish.altavista.com/tr</a>
ETH.MESH.PM.000001 - Prolift Professional Education Videos
ETH.MESH.PM.000002 - TTV-O Procedural Video
ETH.MESH.PM.000006 - Anatomy Videos

**Production Materials**

ETH.MESH.PM.000007 - Prolift Professional Education Videos
ETH.MESH.PM.000009 - Anatomy Videos
ETH.MESH.PM.000014 - Prolift Professional Education Videos
ETH.MESH.PM.000015 - Prolift Professional Education Videos
ETH.MESH.PM.000019 - Prolift Professional Education Videos
ETH.MESH.PM.000027 - Prolift Professional Education Videos
ETH.MESH.PM.000032 - Prolift Professional Education Videos
ETH.MESH.PM.000033 - Prolift Professional Education Videos
ETH.MESH.PM.000034 - Prolift +M Professional Education Videos
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ETH.MESH.PM.000038 - Prolift Professional Education Videos
ETH.MESH.PM.000039 - Prolift Professional Education Videos
ETH.MESH.PM.000042
ETH.MESH.PM.000045
ETH.MESH.PM.000048 - Prolift +M Professional Education Videos
ETH.MESH.PM.000057 - Anatomy Videos
ETH.MESH.PM.000058 - Prolift Professional Education Videos
ETH.MESH.PM.000059
ETH.MESH.PM.000065 - Prolift Professional Education Videos
ETH.MESH.PM.000068 - Anatomy Videos
ETH.MESH.PM.000075 - Prolift Professional Education Videos
ETH.MESH.PM.000076 - Prolift Professional Education Videos
ETH.MESH.PM.000078 - Prolift Professional Education Videos
ETH.MESH.PM.000083
ETH.MESH.PM.000084
ETH.MESH.PM.000087
ETH.MESH.PM.000088 - Anatomy Videos
ETH.MESH.PM.000089 - Anatomy Videos
ETH.MESH.PM.000090 - Anatomy Videos
ETH.MESH.PM.000092 - Prolift +M Professional Education Videos
ETH.MESH.PM.000093
ETH.MESH.PM.000094
ETH.MESH.PM.000095
ETH.MESH.PM.000096
ETH.MESH.PM.000097
ETH.MESH.PM.000098
ETH.MESH.PM.000130
ETH.MESH.PM.000134 - Anatomy Videos
ETH.MESH.PM.000143
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ETH.MESH.PM.000148
ETH.MESH.PM.000151 - Anatomy Videos
ETH.MESH.PM.000154 - Anatomy Videos
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ETH.MESH.PM.000157
ETH.MESH.PM.000170
ETH.MESH.PM.000171

**Production Materials**

ETH.MESH.PM.000179 - TTV Secur IFU V5e 2005 to disc (Original from Prof Ed DVD)
ETH.MESH.PM.000179 - TTV-Secur Key Tech Points 5.24.2007 (Color Oringinal from Prof Ed DVD)
ETH.MESH.PM.000190 - Prolift Professional Education Videos
ETH.MESH.PM.000192 - Prolift Professional Education Videos
ETH.MESH.PM.000202
ETH.MESH.PM.000246
ETH.MESH.PM.000257
ETH.MESH.PM.000272
ETH.MESH.PM.000273
ETH.MESH.PM.000274
ETH.MESH.PM.000288
ETH.MESH.PM.000303
ETH.MESH.PM.000306
ETH.MESH.PM.000309
ETH.MESH.PM.000316
ETH.MESH.PM.000317
ETH.MESH.PM.000318
ETH.MESH.PM.000319
ETH.MESH.PM.000320
ETH.MESH.PM.000321
ETH.MESH.PM.000322
ETH.MESH.PM.000336
ETH-00254-261 - Patient Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2006
ETH-00295-300 - Exh. 10 Gynecare Prolift IFU dated 2004
ETH-00797-829 - 510(k) Notification Gynemesh Prolene™ Soft Nonabsorbable Synthetic Surgical Mesh.
ETH-00807-808 - FDA Clearance letter for Gynemesh soft mesh for pelvic floor repair
ETH-00830-861 - Labeling/Package Insert
ETH-00862-893 - Test Method for the Determinartion of Mesh Burst Strength for Prolene Soft Mesh.
ETH-00894-927 - Medical Literature
ETH-01363-365 - Exh. 15 Letter to Bryan Lisa from Mark M. Melkerson with FDA stamped 5.15.08 re: K071512 Gynecare Prolift with attached 510(k) K071512
ETH-01816-817 - FDA Clearance Letter, Prolene Soft Mesh (K001122)
ETH-02386 - Cosson, M. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results
ETH-02387 - Lucente, V. Prospective clinical assessment of the total vaginal mesh (TVM) Technique for treatment of pelvic organ prolapse - 6 and 12 month results.
ETH-02388 - Amblard, J. From the TVM to the Prolift® (Gynecare): evolution of a technique for prosthetic support to treat prolapse via the vaginal route, concerning a retrospective multicentric series of 794 patients (684 TVM/110 Prolift)
ETH-02653 - Fatton, B. Preliminary results of the "Prolift™" Technique in the treatment of pelvic organ prolapse by vaginal approach: a multicentric retrospective series of 110 patients. IUGA 2006 Athens Non-discussed Abstract 275
ETH-02750-755 - Hinoul P. A Prospective Study to Evaluate the Anatomic and Functional Outcome of a Transobturator Mesh Kit (Prolift Anterior) for Symptomatic Cystocele Repair. Journal of Minimally Invasive Gynecology (2008) 15, 615-620

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ETH-03220-221 - Cosson, M. Preservation of uterus when treating prolapse by Prolift TM does not significantly reduce risk of early post-surgical complications and failures. ABS 89
ETH-03223 - Dedet, B. Transvaginal repair of genital prolapse by the Prolift technique: outcome one year after surgery.
ETH-03227-228 - Dati, S. Prolift vs. Avaulta for transvaginal repair of severe pelvic prolapse
ETH-03568-578 - (03.01.2005) Summary Memo for Revision B of the Gynecare Prolift Design Failure Modes Effects Analysis (dFMEA).
ETH-07153-158 - Gynecare Prolift Clinical Expert Report signed by Charlotte Owens on 01.14.05.
ETH-07247-303 - (03.02.2005) Approvals and Summary Memo for Version A of the Gynecare Prolift Application Failure Modes Effects Analysis (aFMEA).
ETH-07252-281 - Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique
ETH-10437-449 Gynemesh PS IFU
ETH-10505-596 - 2008 Prolift Slide deck
ETH-10977-983 - Gynecare Prolift IFU dated 2009
ETH-18415 - Memo to Hospital Materials Managers & or Directors from Gynecare Worldwide Ethicon dated 10.10.02 regarding Gynecare Gynemesh*PS
ETH-37788-793 - Gynecare Prolift Clinical Expert report
ETH-60188-195 - Hiltunen R. Low-Weight Polypropylene Mesh for Anterior Vaginal Wall Prolapse - A Randomized Controlled Trial. Obstet Gynecol 2007;110:455-62
Ethicon Final Report, PSE Accession No. 00-0035 An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE Acc. No. 00-0035)
Ethicon Technical Report: Assessment of Competitor Pelvic Floor Repair Meshes, Version 1; Study Number: CPC-2006-0552; JJ-HMREV-00016715
Ethicon Women's Health & Urology — Clinical Compendium — Sales Rep Positioning [ETH.MESH.0011879; ETH.MESH.00093830]
EWHU Faculty and PF User Conference Calls Outline
Exh. 59 - Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile (2 pages)
Guidance for Industry and FDA Staff. "Class II Special Controls Guidance Document: Surgical sutures; Guidance for Industry and FDA."
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance. "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience dated in 2003 (8 pgs)
Gynecare Gynemesh PS IFU (English Only) LAB-0012266 Rev: 3, released 02.03.15.
Gynecare Prolift - Product Device Design Safety Assessment (DDSA)
Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique (30 pgs)
Gynecare Prosima - Content for Ethicon360.com
Gynecare Prosima (K063562) Summary of Safety and Effectiveness
Gynecare Prosima updates to ethicon360.com
Gynecare TTVT IFU changes redlined, D-6, 1-20
Gynemesh PS 510k Approval File [FDA]
Gynemesh PS Approval File (FDA) Requested August 15, 2007 Folder: K013718 - 131 pages; Summary: Product: GYNEMESH PROLENE SOFT (POLYPROPYLENE) NON ABSORBABLE SYNTHETIC SURGICAL
Gynemesh PS Approval File from FDA website (K013718)

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Gynemesh PS white paper - Early Clinical Experience
HMESH.ETH.11642462 - Franchise Regulatory Labeling Guidance
JJM.Mesh.00043703 Response Statement and FAQS - FDA Notification about use of surgical mesh to treat pelvic organ prolapse and stress urinary incontinence
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
K013718 GYNEMESH PS (Ethicon) Corrected SE Letter (07-Nov-2012)
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Letter from FDA re: Postmarket Surveillance (PS) Study: PS120044 (Prosima 522 Order)
Letter to EWHU Field Sales Force from Price St. Hilaire dated 10.23.06 re: criteria for surgeons being trained for Gynecare Prolift (1 pg)
Letters to and from the FDA re: Prolene, Polypropylene Nonabsorbable Surgical Suture, USP.
Librojo updated TTV Declaration (10-23-15) [12 pages]
May 2010 CER for Gynemesh PS signed by David Robinson
McCabe email re - Sheath Sales Tool - 464
Memo to S. Ciarrocca re: Regulatory Strategy - Project D'Art; Rev 3
Mesh Information for Patients with Pelvic Floor Disorders
MSDS-Marlex Polypropylenes
Notice of Claimed Investigational Exemption for a New Drug (1-125)
Notice of Claimed Investigational Exemption for a New Drug (126-253)
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]
Pelvic Organ Prolapse Patient Counseling Guide
Powerpoint - GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
Powerpoint - Prospective Clinical Assessment of TVM - 1 Year Results
Powerpoint Presentation entitled "Trocars & Pelvic Anatomy: Do They Mix Well?"
Presentation: Non Absorbable Sutures
Prosima Complaints PPM_REV_0103350
Prosima IFU Book
prosima training deck 1
Prosimma training deck 2
PS120046 A2 - 7.9.12 FDA Response to Ethicon re Gynemesh PS
Published clinical data and RCTs - Ethicon.com - 4204-C
Seven Year Dog Study - T-2263
Slide Presentatopm "Gynecare Prosima ™ Pelvic Floor Repair System
Summary of Safety and Effectiveness submitted by Bryan Lisa for Gynecare Prolift and Prolift +M stamped 5.15.08 (2 pgs)
Supplement Numbers and Application Dates
Surgeon's Rescourse Monograph for TTV
TVM Prospective 6 month Data
TTV Abbrevio IFU - 01.2015
TTV Exact IFU - 01.2015
TTV IFU - 01.2015
TTV IFU (7th version) 2015 - Present - from Ethicon website.
TTV Patient Brochure - 2015

**Production Materials**

TVT-O la bandelette trans-obturatrice (Photograph)
TVT-Obturator IFU - 01.2015
TVT-R Prof Education Slide Deck
Video titled Prosima Shortened Procedure. Hydrodissection and Dissection.
Video: 2010 Prosima Testimonial for NTM
Wound Closure Manual

**Company Witness Depositions**

<b>Deponent [Date of Deposition]</b>
Angelini, Laura [09.16.2013]
Angelini, Laura [09.17.2013]
Angelini, Laura [11.14.2013]
Arnaud, Axel [11.15.12]
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Austin, Charles E. - 08.13.2015
Barbolt, Thomas [1.7.2014]
Barbolt, Thomas [1.8.2014]
Barbolt, Thomas [8.14.2013]
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Barbolt, Thomas Ph.D. [10.10.12]
Barbolt, Thomas Ph.D. [10.9.12]
Batke, Boris [8.1.2013]
Batke, Boris [8.2.2013]
Beach, Patricia [6.17.13]
Beath, Catherine [11.8.12]
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Brown, Allison [9.11.13]
Burkley, Dan F [5.22.2013]
Burkley, Dan F [5.23.2013]
Burkley, Daniel [10.2.12]
Butts, Lebron [8.21.14]
Cecchini, Peter [10.22.2013]
Cecchini, Peter [10.23.2013]
Chahal, Ricky [12.10.2014]
Chen, Meng [10.29.2013]
Chen, Meng [10.3.12]
Chen, Meng [10.30.2013]
Chen, Meng [10.4.2012]
Courts, Paul [6.11.15]
Elbert, Katrin [12.23.14]
Elbert, Katrin, Ph.D. [12.23.2014]
Gauld, Judith [11.8.13] [4.27.12]
Grier, Douglas [12.30.2014]
Hart, James [12.20.13]
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Hinoul, Piet [01.13.2014]
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Hinoul, Piet M.D., Ph.D. [4.5.12]
Hinoul, Piet M.D., Ph.D. [4.6.12]
Hinoul, Piet M.D., Ph.D. [9.18.12]
Hinoul, Piet M.D., Ph.D. [9.19.12]
Holste, Joerg [12.14.12]
Holste, Joerg [12.15.12]
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Holste, Joerg [7.30.2013]
Horton, Ronald, M. - 07.01.2015
Isenberg, Richard [11.05.2013]
Isenberg, Richard [11.06.2013]
Jones, Gregory R [8.20.2013]
Kammerer, Gene [01.17.2014]
Kammerer, Gene [01.28.2014]
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Kanerviko, Brian [8.23.13] [8.22.13]
Kirkemo, Aaron [01.06.2014]
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Owens, Charlotte [6.19.2013]
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Owens, Charlotte M.D. [9.12.12]
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Parisi, Paul [6.6.13]
Peebles, Rhonda [07.16.2014]
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Robinson, David [7.24.2013]
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Schmid, Tim - 07.31.2015
Selman, Renee Elayne [6.20.2013]
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Smith, Dan J [2.3.2014]
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Volpe, Clifford [2.28.12] [2.29.12]
Walji, Zenobia [3.7.12]
Weisberg, Martin - 11.12.2015 Deposition Testimony
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## Other Materials

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02.01.2012 Prosima 522 cover letter
02.01.2012 Prosima Postmarket Surveillance Study PS120044; Gynecare Prosima Pelvic Floor Repair System
02.25.2016 Brief Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee
07.13.2011 - FDA Public Health Notification
07.25.2011 SGS - Executive Committee Statement Regarding the FDA Communication: Surgical placement of mesh to repair pelvic organ prolapse imposes risks.
2007 No. 79 ACOG Practice Bulletin POP
2007 No. 85 ACOG Practice Bulletin POP
2009 AUA Prosima Slide - A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. (Zyczynski, H.)
2009 IUGA Prosima Slide - A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. (Slack, M.)
2010 AUA Update Guideline for the Surgical Management of Stress Urinary Incontinence
2011 ACOG Committee Opinion 513 - Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse
2011 ACOG Committee Opinion: Vaginal placement of synthetic mesh for pelvic organ prolapse.
2011 AUA Position Statement on the Use of Vaginal Mesh for SUI
2011 Khandwala ICS Poster - Prosima
2012 ABOG Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2013 AUGS Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse
2013 AUGS Position Statement on Restriction of Surgical Options for Pelvic Floor Disorders
2013 Oct. AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of SUI
2013 RANZCOG - UGSA Position Statement on Vaginal Mesh (Rewrite Executive March 2013) C-Gyn 20 Polypropylene Vaginal Mesh Implants for Vaginal Prolapse
2013 Sept. NICE 171 Guideline - The management of urinary incontinence in women
2014 Jan - AUGS-SUFU MUS Position Statement APPROVED 1 3 2014
2014 Mar 12 - AUGS SUFU Provider FAQs MUS for SUI
2015 Mar EAU Guidelines on Urinary Incontinence
2015 SCENIHR Report, EU Commission FULL – Opinion on The safety of surgical meshes used in Urogynecological surgery.
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# **Christina Pramudji**

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***in Addition to Materials Referenced in Report***

**Barbara Smith**

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Zhu L, et al. [Pop 21, 18-60 mos, median 43.5 mo fu] Modified laparoscopic sacrocolpopexy with mesh for severe pelvic organ prolapse. Int J Gynecol Obstet 2013; 121: 170-172.
Zhu L, Lang J, Hai N, Wong F. Comparing vaginal tape and transobturator tape for the treatment of mild and moderate stress incontinence. Int J Gynaecol Obstet 2007; 99(1): 14-17.
Zullo MA, Plotti F, Calcagno M, Marullo E, Palaia I, Bellati F, Basile S, Muzii L, R Angioli R, Panici PB. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TTV-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007; 51(5): 1376-82; discussion 1383-4.
Zyczynski HM, et al. (Prosima Study investigators) One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol 2010; 203: 587.e1-8.
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Zyczynski HM, et al. Sexual activity and function in women more than 2 years after midurethral sling placement. Am J Obstet Gynecol 2012; 207: 421.e1-6.

**Production Materials**

<b>Document Description [Bates Range]</b>
000001_4275674_d_Use of Gynemesh PS in Prolapse Surgery Power Point
2000 June TVT Surgeons Resource Monograph
2003 Gynemesh PS Early Clinical Experience White Paper
2003 Gynemesh PS white paper. Gynemesh PS Early Clinical Experience.
2004 Gynemesh PS Study Poster - AUGS 2004 San Diego. Luente V, Hale D, Miller D, Madigan J. A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse.
2005 Prolift Prof Ed Slide deck (P's Exhibit 127)
2005-2006 Gynecare Prolift Pelvic Floor Repair Systems - slides (16 pages)
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
2007 & 2008 Gynecare Prolift Pelvic Floor Repair Systems - slides (46 pgs)
2007 Prolift Prof Ed Slide deck (P's Exhibit 128)
2007 Prolift Surgeon Monograph
2007 Surgeon Monograph
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
9.22.2011 Letter to surgeons
A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse by V. Luente, et al. 1 pg
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
Australian Pelvic Floor Discussion
Benefit Risk Profile of Transvaginal Mesh Products Used for the Treatment of Pelvic Organ Prolapse signed by Piet Hinoul dated 6/21/2012
Brigitte Fatton Powerpoint Presentation entitled "Complications in Pelvic Floor Dysfunction Surgery: evaluation and management.
Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2005 (8 pgs)
Brochure Treatment Options for Pelvic Organ Prolapse Stop coping. Start living. Dated in 2008 Gynecare Prolift (15 pgs)
Classification Website Intro "An International Urogynecological Association (IUGA/Internation Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertionm of Prostheses (Meshes, Implants, Tapes) & Grafts in Female Pelvic Floor Surgery."
Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013
Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.
D00001256-2005 Prolift Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems) [Native Format]
D00001260-2007 and 2008 Prolift and M Prof Ed.pdf (Gynecare Prolift: Pelvic Floor Repair Systems)[Native Format]
Dear Surgeon Letter from Piet Hinoul and Aaron Kirkemo.
Declaration of Reynaldo Librojo
Declaration of Reynaldo Librojo in Support of Motion for Summary
Declaration of Thomas A. Barbolt, Ph.D., DABT, 1981-2011 in Support of Motion for Summary Judgement
DEFT 19.1-19.6 - Prolift M IFU
DEFT 730.1-730.72 - 2007 Prolift Surgeons Monograph

## Production Materials

DEPO.ETH.MESH.00004755 - Guidoin Explant
Document entitled "Delay in Prosima Activities"
Document entitled "Pelvic Floor Repair. Extended Review of Medical Literature."
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
DX25662.71 - Prolift Design Validation
Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2
Email string re: Revised write up of the DeLeval and Waltregny visit
Email string re: Ultrapro vs Prolene Soft Mesh
Email string, top one from Gary Pruden to David Robinson, et al. re: article entitled :Vaginal repair with mesh no better than colporrhaphy for pelvic organ prolapse.
ETH.MESH.00000172 - 8/25/11 Email from Marie Hobson to Kevin Frost attaching registration list for call
ETH.MESH.00000173 - 8/25/11 Registration list for 8/25/11 call
ETH.MESH.00001595-606 - Reisenauer, C. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. Eur J Obst Gynecol Reprod Biol 2006
ETH.MESH.00003895 - Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee
ETH.MESH.00012009-074 - Cosson, M. Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse(French 1 year CSR)
ETH.MESH.00012009-089 - Clinical Study Report: Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse.
ETH.MESH.00012090-163 - Robinson, D. Clinical assessment of the TVM technique for treatment of genital prolapse. Final Report of 12-month evaluation. (US 1 year CSR)
ETH.MESH.00013529-534 - Prolift+M IFU
ETH.MESH.00016032-039 - Kohli, N. Augmenting pelvic floor repairs. 2006 Supplement to OBG Management
ETH.MESH.00017362-368 - Elmer C, et al. Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery, J Urol (2009), 181 (3), 1189-95.
ETH.MESH.00017553-560 - Tunuguntla, H. Female Sexual Dysfunction Following Vaginal Surgery: A Review. Journal of Urology 2006; 175: 439-446
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00019117-121 - Letter from Scott H. Jones to Price St. Hilaire re: Prosima US Launch Plan; cc: Renee Selman, et al.
ETH.MESH.00020763 - Prolift +M Profession Education Slide Deck
ETH.MESH.00020764 - Prolift +M Profession Education Slide Deck
ETH.MESH.00031323 - Memo to Customer from Sean M. O'Bryan dated 2.8.05 regarding Gynecare Prolift
ETH.MESH.00031324-325 - Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair

## Production Materials

ETH.MESH.00064002-004 - Email string, top one from Judith Gauld to Scott Jones re: US preceptors for Prosima.
ETH.MESH.00064054 - Gynecare Prosima ™ Pelvic Floor Repair System - Global Launch Strategy
ETH.MESH.00064138-139 - Document entitled "PROSIMA Critical Success Factors."
ETH.MESH.00071755 - Prosima - Apical Support Learning Guide
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00076167 - Letter from Bryan Lisa to Dan Smith re: Prosima Product Release Authorization; cc: Stephanie Kute, Jennifer Paine.
ETH.MESH.00076710-790 - Clinical Study Report. Evaluation of Prosima for Pelvic Organ Prolapse. Protocol Number: 300-06-005. "A Prospective, Multi-centre Study to Evaluate the Clinical Performance of Gynecare Prosima Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse."
ETH.MESH.00077073-093
ETH.MESH.00077094-111
ETH.MESH.00077395
ETH.MESH.00077739 - Prosima Story
ETH.MESH.00078114-115 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.00081288-289 - Memo to Jennifer Paine, et al from Renee Selman dated 1.16.08 regarding Project Lightning Status
ETH.MESH.00082651-654 - Email string, top one from Marcus Carey to J. Meek, D. Robinson, P. Hinoul,et al. re: Technical feedback on Prosima.
ETH.MESH.00083812-814
ETH.MESH.00086463-465 - E-mail from Piet Hinoul to Zeb Viana, et al. regarding TR: PROSIMA TAKE AWAY MESSAGES; cc: Bart Pattyson, et al.
ETH.MESH.00093526-544 - Prolift +M Profession Education Slide Deck
ETH.MESH.00093991 - Prolift +M Profession Education Slide Deck
ETH.MESH.00108120-121 - Email string, top one from Douglas Grier to Lissette Caro-Rosado, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson.
ETH.MESH.00125373 - Email string, top one from Tom Eagan to Erin Haggerty re: Dr. Sepulveda.
ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on Prolift+M for input
ETH.MESH.00127103 - Email from Greg prine to Scott Jones, Jonathan Meek re: Prosima Road Show; cc: Lesley Fronio and Kevin Mahar.
ETH.MESH.00127125-126 - Email From Lewis to Mahar, et al. re: How did Dr. Grier's Prosima cases go?
ETH.MESH.00129102 - Suggested Remarks - Incontinence and Pelvic Floor Summit What a Difference a Decade Makes
ETH.MESH.0013114-151 - Email string, top one from Stephanie Grupe to Kevin Mahar re: Prosima Global Launch Team.
ETH.MESH.00144449 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00184127 - 2012.11.28 TVT Exact Prod Ed Deck (TVTE-129-11-3.13)

## Production Materials

ETH.MESH.00220335-336 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients e: Pre-Reading for Prolift+M: Internal Use Only. Not Copy Reviewed or For Distribution
ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.
ETH.MESH.00281482-484
ETH.MESH.00295355 - 2010 TTVT Exact Prof Ed
ETH.MESH.00303310-313 - Memo from Dan Lamont to Gynecare Prosima Risk Management Report (RMR-0000029) re: Pelvic Floor Product(s) Complaint Review for Gynaeacre Prosima Risk Management.
ETH.MESH.00308094 - 2006 TTVT-Secur (2629_2006-07-12)
ETH.MESH.00310205 - Product Quality Issue re: Prosima signed by Mark Yale.
ETH.MESH.00310206 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).
ETH.MESH.00316849-850
ETH.MESH.00318930 - (Draft) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00318934 - Document entitled " Delay in Prosima Activities."
ETH.MESH.00326911 - Ethicon Delayed Prosima Launch by Two Years
ETH.MESH.00329474-509 - Project Mint Design Review
ETH.MESH.00335084-085 - Email from Daniel Lamont to Sungyoon Rha, et al. re: Mint Functional Strategies.
ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on the Tension Free Vaginal Tape (TTV) System for Compliance to FDA G-95/ ISO 10993/ EN 30993
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TTV (Ulmsten) Device
ETH.MESH.00354732 - Gynecare TTV Abbreviated Professional Education.
ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.00369995 - 2008 TTV Family of Products
ETH.MESH.00369999 - 2008 TTV-Secur (2008-135)
ETH.MESH.00370315 - Prosima Training Deck 1
ETH.MESH.00370421 - TTV-O FDA Public Health Notice (TVTO_0113-09-8.11)
ETH.MESH.00371595-903 - Prosima 510(k) and Clearance letter
ETH.MESH.00372564-568 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number 2003-016
ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)
ETH.MESH.00373310-388 - 2003 TTV Support for Incontinence General Prof Ed Deck
ETH.MESH.00393045-046 - TTV-O Procedural Steps
ETH.MESH.00394849 - Gynemesh PS Panel Powerpoint - Drs. Robinson, Miller, Winkler, England
ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL, June 22, 2001
ETH.MESH.00397674 - 2002 Dr. Miklos Minimizing and Managing TTV Complications
ETH.MESH.00405513-514

## Production Materials

ETH.MESH.00409158 - (Official) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00418855-856 - Email string, top one from Andrew Meek to Jonathan Fernandez, et al. re: Prosima Preceptor Recommendation Form; cc: Kevin Frost, et al.
ETH.MESH.00424374-375 - Email string, top one from Jonathan Fernandez to Rhonda Peebles re: remaining 2010 labs; cc: Robert Zipfel.
ETH.MESH.00426441 - Email from Kevin Frost to Robert Zipfel, et al. re: Prosima 2-year slide deck; cc: Paul Parisi.
ETH.MESH.00442129 - PowerPoint Mechanical vs. "Machine"-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammerer
ETH.MESH.00455676-677 - Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima Jan 2007 update; cc: Bob Roda, et al.
ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force
ETH.MESH.00467320 - Email string, top one from Andrew Meek to Bart Pattyson, Paul Parisi re: November Lab.
ETH.MESH.00484929 - 2005-2006 Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.00484929 - 2007 & 2008 Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.00495796-798 - Email string, top one from Jennifer Paradise to Melissa Doyle, et al. re: Prof Ed through Tele-Mentoring; cc: Paul Parisi, et al.
ETH.MESH.00510562-563 - Email string, top one from Kevin Frost to DL-ETHUSO EWHU DMs, et al. re: 1st Prosima Virtual Round Table Tomorrow; cc: Matt Henderson, et al.
ETH.MESH.00516424-427
ETH.MESH.00520649-722 - 2006 US TVM 12 Month Clinical Report
ETH.MESH.00523617 - 2007 TVT-Secur Critical Steps (2007-4144)
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00526473-474 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00541379-380 - Mesh Fraying for TTV Devices
ETH.MESH.00541708-709 - Document entitled "Notes from Competitive Ad Board."
ETH.MESH.00541873 - Chart listing Proposed Lab Scheduling for August 4th.
ETH.MESH.00541876-878 - Email string, top one from Bart Pattyson to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.
ETH.MESH.00542347-348 - Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.
ETH.MESH.00542463 - Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: 2-Year Clinical Data
ETH.MESH.00547021 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.00547036-037 - Email string, top one from Bart Pattyson to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.
ETH.MESH.00547500-501 - Email re: 69% Success
ETH.MESH.00573815 - Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima* Pelvic Floor Repair System) June 2010.
ETH.MESH.00573860-878 - (Draft) Sayer, T., et al. "Medium-term Clinical Outcomes Following Surgical Repair for Vaginal Prolapse with Tension-free Mesh and Vaginal Support Device."
ETH.MESH.00575257 - Abbrevio laser cut vs. mechanically cut - notes from meeting with de Leval - inappropriate

## Production Materials

ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00575580-581 Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.
ETH.MESH.00575634-635 - ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."
ETH.MESH.00575818-820 - Piet email re Prolift
ETH.MESH.00578081-083 - Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.
ETH.MESH.00578550 - (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."
ETH.MESH.00579296 - Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolapse Patients.
ETH.MESH.00580588-589 - Email string dated 3/25/2010, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch
ETH.MESH.00580711-713 - Email re: Piet explains PS in Prosima
ETH.MESH.00584811-813 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00591563-565 - Email re: Smelly VSDs
ETH.MESH.00592224-229 - E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima
ETH.MESH.00592585-587 - Email re: No RCT for Prosima
ETH.MESH.00594266 - Email re: Overstating Success - Less Misleading
ETH.MESH.00594455 - Email re: Stop communicating over email
ETH.MESH.00594528 - Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commerical claims of 92.3% above the hymen.
ETH.MESH.00595468-470 - Goldman, H., FitzGerald, M. "Opposing Views: Transvaginal Mesh for Cystocele Repair," J Urol (2010) 183:430-432.
ETH.MESH.00595889-890 - Email string, top one from Kevin Frost to Aaron Kirkemo re: Prosima presentation; cc: Tom Affeld.
ETH.MESH.00604183-186 - Email string, top one from Piet Hinoul to Judi Gauld and Colin Urquhart re: PISQ, and score when unable to have sex.
ETH.MESH.00631782-784 - FDA Letter re: K063562 Gynecare Prosima
ETH.MESH.00637343 - 2004 ETHICON Product Development Process - Gynemesh PS
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00662233 - Email from Scott Jones to DL-Ethusso dated 12/15/2009 re: PAGS Leads
ETH.MESH.00679637-640 - Email string, top one from Zenobia Walji to Ron Naughton, et al. re: Prolene Soft Mesh '05 proposed pricing; cc: Kevin Maher, et al.
ETH.MESH.00687819-822 - Email string re-Laser cut mesh
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev.
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev. 2
ETH.MESH.00754928-5001 - 2010 May - TVT Exact Design Validation Report.Protocol
ETH.MESH.00759327-335 - Document entitled "Experience what's new in incontinence and pelvic floor repair." 2010 ICS IUGA Executive Agenda
ETH.MESH.00776993-7000 - Prosima Sales Aid

**Production Materials**

ETH.MESH.00791497 - Email re Prosima Brochure and DVD
ETH.MESH.00800521-522 - Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.
ETH.MESH.00806974-975 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.00807570 - Revised Chart listing Proposed Lab Schedule
ETH.MESH.00807772-774 - Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.
ETH.MESH.00807972-973 - Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.00808121-122 - Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.
ETH.MESH.00817181 - Email dated 1/22/2010 from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.
ETH.MESH.00820634 - Invitation to participate in Gynecare Prosima Virtual Round Table
ETH.MESH.00826114 - 2005 Dec 5 D. Robinson email regarding voiding and Prolift
ETH.MESH.00832749-754 - Risk Management Report: Prosima Pelvic Floor Repair Kit
ETH.MESH.00833948-949 - Email from David Robinson to Jessica Shen re: Prosima Study.
ETH.MESH.00834910-911 - Email string , top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.
ETH.MESH.00840886-887 - Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.
ETH.MESH.00843043 - Email from David Robinson to Jacqutin Bernard, Judith Gauld and Jonathan Meek re: cancellation of scheduled Prosima training.
ETH.MESH.00848020-021 - 2006 Jan 27 D. Robinson email regarding voiding and Prolift
ETH.MESH.00849014-017
ETH.MESH.00850335-336 - Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.
ETH.MESH.00851319-321 - Email string, top one from P. Hinoul to C. Volpe, et al. re: Prosima implant dimensions.
ETH.MESH.00856579-582 - E-mail string dated 11/3/2010 re: neo clinical trial. Piet Hinoul: "Each individual study does not contribute to the success of those products
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858096-097 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-253 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00860239-310 - TVT-O IFU
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.00895089-091 - Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.
ETH.MESH.00916799 - Project MINT Charter Review
ETH.MESH.00921692-694 - Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.

## Production Materials

ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement
ETH.MESH.00925065-067 - Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.
ETH.MESH.00991195-257 - Clinical Study Report Evaluation of the TVM technique for treatment of genital prolapse Protocol Number CT-TVM-001-03
ETH.MESH.00993273 - 2006 TTVT-O Summit Presentation by Raders and Lucente
ETH.MESH.00993273 - TTVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.01075187-215 - Clinical Expert Report Gynecare Prolift Pelvic Floor Repair System dated 7.2.10
ETH.MESH.01128679-698 - 2007 TTVT-Secur Procedural Steps (TVTS007)
ETH.MESH.01136239-240 - Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.
ETH.MESH.01154031-037 - Clinical Expert Report - Gynemesh Prolene Soft
ETH.MESH.01198058 - (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."
ETH.MESH.01200286 - Powerpoint: Gynecare Prosima : Overview.
ETH.MESH.01201973 - Proposed Lab Schedule (2nd Revision)
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203957-997 - The future of surgical meshes-the industry's perspective
ETH.MESH.01212972 - Hinoul presentation Incontinence Overview
ETH.MESH.01219542-548 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-145 - Email string re-New Standards for Urethral Slings
ETH.MESH.01228079-084 - Nilsson Podcast Transcript
ETH.MESH.01237077-079 - Email dated 9/3/2009 from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier
ETH.MESH.01238454-456 - Email string re-TVTO length
ETH.MESH.01244824-826 - Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.
ETH.MESH.01261962 - TTVT-O Summit by Raders, Rogers, Lucente (2005-1819)
ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009
ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.
ETH.MESH.01279975-976 - (P041566) Harel Gadot Email re Next step in SUI sling
ETH.MESH.01310817-829 - Ethicon Biocompatibility Risk Assessment for Gynecare Prolift Total Pelvic Floor Repair System dated 1.19.05
ETH.MESH.01317508-613 - TTVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01320328-333 - Performance Evaluation of TTVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
ETH.MESH.01320351-367 - Corporate Product Characterization Plan, TTVT-Laser Cut Mesh. Dated 02/06/2006
ETH.MESH.01411037-039 - Summary re: Project Mint
ETH.MESH.0141137-139 - Document re: summary of changes in mesh implant from Project Mint to final production.

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ETH.MESH.01593930-942 - Prosima Clinical Expert Report (not signed or dated).
ETH.MESH.01595614-753 - Prolift +M IFU
ETH.MESH.01612323-333 - Patient Brochure: Pelvic Organ Prolapse "Get the Facts, Be Informed, Make Your Best Decision."
ETH.MESH.01638150 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System Backrgound; Halina Zyczynski, M.D.
ETH.MESH.01678340 - Email from Andrew Meek to Melissa Doyle et al. re: Approved Prosima Receptors.
ETH.MESH.01707963 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.01708116-117 - Email string, top one from Bart Pattyson to Georgia Long re: TVT Abbrevio and Prosima training; cc: Elizabeth Kolb, Andrew Meek.
ETH.MESH.01708180 - Chart listing financial information re: preceptors.
ETH.MESH.01708190 - Chart listing financial information re: preceptors.
ETH.MESH.01730626-629 - Email string, top one from Dr. Antar to Bart Pattyson re: Prosima presentation.
ETH.MESH.01733531-535 - Kasturi, S. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203: 1.e1-1.e5
ETH.MESH.01752532-535 - Mesh design argumentation issues
ETH.MESH.01775482 - Prosima letter delying launch
ETH.MESH.01776504-510 - Email re: 60% Success
ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.
ETH.MESH.01782783-785 - (02.02.2006) Notes from meeting with Dr. V. Luente and Dr. M. Murphy (Allentown, PA) to discuss Prolift RCT.
ETH.MESH.01784823-828 - Clinical Expert report-Laser Cut Mesh
ETH.MESH.01785259-260 - Email dated 1/17/2010 from Dr. Piet Hinoul to Dr. David Robinson, et al. Re: +M relaxation
ETH.MESH.01803816-818 - Summary re: Project Mint
ETH.MESH.01804533-535 - 2003 TVT-O IFU Verification by surgeons
ETH.MESH.01808311-318 - (P041370) Trip Report from Michael Tracey, Principal Engineer -TVT-O de Leval study
ETH.MESH.01809082-083 - Memo re: VOC on new laser cut TTV mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-978 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01821586-587 - Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Dan Smith, et al.
ETH.MESH.01822361-362 - Dan Smith Email regarding TTV-Secur leading to less retention
ETH.MESH.01822361-363 - Dan Smith Email regarding TTV Secur October 18, 2006
ETH.MESH.02001398-404 - Gynecare Prolift IFU (English Only)
ETH.MESH.02001398-473 - Prolift IFU
ETH.MESH.02010349-362 - Prosima Clinical Expert Report signed by David Robinson
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ETH.MESH.02020023-024 - Prosima ISO cytotoxicity biocompatibility
ETH.MESH.02026591-595 - MSDS-c4001 Polypropylene Homopolymer

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ETH.MESH.02066770-771
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02092919-921 - Prosima Clinical Strategy
ETH.MESH.02105765-771 - FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence issued 10.20.08; Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence posted by FDA dated 10.23.08 at bottom; Information on Surgical Mesh for Hernia Repairs posted by FDA dated 10.23.08
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ETH.MESH.02156379-380
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ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh.
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ETH.MESH.02215565-567 - Email from Scott Ciarrocca to multiple recipients re: a message from Barbara Schwartz re: Prolift (01.02.2005).
ETH.MESH.02217343-344
ETH.MESH.02219584 - Scion PA/SUI Treatment Unmet Needs - Exploratory Research, Presented 22 January 2010
ETH.MESH.02229013 - Email re: IFU errors
ETH.MESH.02229051 - Video: "Biomechanics"
ETH.MESH.02229054 - Video: "What to Expect"
ETH.MESH.02229055 - Video: "VSD Case Series 1"
ETH.MESH.02232685 - Marketing: "Your Proof: Her dance class."
ETH.MESH.02232773-801 - Prolift+M Profession Education Slide Deck
ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion
ETH.MESH.02232854-874 - Prolift+M Profession Education Slide Deck
ETH.MESH.02233126-187 - Prolift+M Educational Module
ETH.MESH.02233126-187 - Prolift+M Profession Education Slide Deck
ETH.MESH.02233290 - Prolift +M Profession Education Slide Deck
ETH.MESH.02233410 - US Launch - Premarket Preparation (PMP) 2009 US Sales Meeting Brief
ETH.MESH.02233417 - Prosima New Product Request Form
ETH.MESH.02233418-438 - Prosima - Surgical Technique
ETH.MESH.02233439-451 - US Training 1-year clinical data: A New Operation for Vaginal Prolapse Reapir Using Mesh and a Vaginal support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study.
ETH.MESH.02233452-467 - Prosima - US Training - Background and Development History
ETH.MESH.02233468-538 - Prosima Prof Ed (71 slides)
ETH.MESH.02233539 - Prosima - New Product Request Form
ETH.MESH.02233540 - Prosima - 2009 Sales Training Program
ETH.MESH.02233605 - (B&W) Webinar Invite "The treatment of Symptomstiv Moderate Pelvic Organ Prolapse."
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ETH.MESH.02233674-692 - (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?"
ETH.MESH.02233699-710 - Prosima - An Interview with Dr. Marcus P. Carey.
ETH.MESH.02233713 - Objective Success Rate Learning Guide
ETH.MESH.02233726-727 - Prosima Product Page on Ethicon-360 12.09
ETH.MESH.02233728 - (native) Gynecare Prosima™ Key Procedural Steps
ETH.MESH.02233751-833 - Prosima Prof Ed 2 (83 slides)
ETH.MESH.02233834 - (B&W) 2009 Sales Aid Guide
ETH.MESH.02233840 - MRI Flashcard "Prosima - The first fixationless mesh system that maintains anatomical position."
ETH.MESH.02233842 - Virtual Round Table Registration Form 9.2010
ETH.MESH.02233843-849 - Clinical Study Findings Discussion for Gynecare Prosima™ by Piet Hinoul (Audio Transcript).
ETH.MESH.02233851-851 - Document entitled "PROS-438-10-9/12 Prosima Short Procedural Video."
ETH.MESH.02233857-859 - AJOG Press Release (Draft)
ETH.MESH.02233862-880 - AALG in booth presentation. "Proof in the Treatment of Pelvic Organ Prolapse" Douglas Van Drie, M.D.
ETH.MESH.02233881-888 - Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.
ETH.MESH.02233956 - Prosima Updates to Ethicon360
ETH.MESH.02233961 - Virtual Round Table Follow-up Letter.
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ETH.MESH.02233963 - Virtual Round Table Invitation 9.2010
ETH.MESH.02233964 - (B&W) Prosima DVD
ETH.MESH.02234001-002 - (Marketing) The Gynecare Prosima™ Pelvic Floor Repair System Story
ETH.MESH.02234005-171 - Prosima Sales Training Program
ETH.MESH.02234173-177 - Prosima Messgaging practice Coaching Check List
ETH.MESH.02234195-196 - Prosima Workshop Takeaway
ETH.MESH.02237107-115 Introducing Gynecare Prosima for Ethicon Epiphany 247.
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both
ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.
ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.
ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.
ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU
ETH.MESH.02293981 - Email from Adrian Roji dated 7/19/11 re Approved FDA Notification Response
ETH.MESH.02318553-554 - Gynecare Prosima™ Combined Pelvic Floor Repair System Clinical Strategy.
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis

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ETH.MESH.02322037-039 - Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial.
ETH.MESH.02330766 - TVT-O (Reproducible Vaginal Approach) (TVTO-384-10-8-12)Production 36_000124_4580875_d
ETH.MESH.02330767 - Marketing Materials for Prosim
ETH.MESH.02340306-369 - TVT IFU
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340471-503 - TVT IFU
ETH.MESH.02340504-567 - TVT IFU
ETH.MESH.02340568-590 - TVT-S IFU
ETH.MESH.02340756-828 - TVT-O IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02340829-901 - TVT-O IFU
ETH.MESH.02340902-973 - TVT-O IFU
ETH.MESH.02340974-1046 - TVT-O IFU
ETH.MESH.02341203-213 - TVT Abbrevo IFU
ETH.MESH.02341398-410 - Prosim IFU (6.18.10 to discontinuance) - English only 13 pages
ETH.MESH.02341398-453 - Prosim IFU
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ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only)
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ETH.MESH.02341522-527 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341522-589 - Prolift IFU
ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341658-733 - Prolift IFU
ETH.MESH.02341734-809 - Prolift 2009-2010 IFU
ETH.MESH.02342097 - Prolene Soft IFU
ETH.MESH.02342101 - Prolene Soft IFU
ETH.MESH.02342102 - Prolene Mesh IFU
ETH.MESH.02342152-154 - Prolene Mesh IFU
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02579701-706 - Email re: Piet re Problem with posterior inserter
ETH.MESH.02596085 - Letters to the Editor 2010; 1457
ETH.MESH.02597949-950 - Hinoul, P., et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine."
ETH.MESH.02599918-920 - Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosim Data Conference Call.
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02614610-624 - Performance Evaluation of TTV U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2
ETH.MESH.02615519-658 - Prolift +M IFU
ETH.MESH.02616825-827 - Prolene Soft IFU
ETH.MESH.02658316 - Cover Letter

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ETH.MESH.02658317-352 - Postmarket Surveillance Study No. PS120043; Gynecare Prolift +M Pelvic Floor Repair Systems; Gynecare Prolift Pelvic Floor Repair Systems
ETH.MESH.02967410-412 - Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.
ETH.MESH.03048942 - Document entitled "New" Mint January 05, 2006.
ETH.MESH.03049774-775 - Gynecare Prosima* Combined Pelvic Floor Repair System: Clinical Strategy.
ETH.MESH.03056578-580 - Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima* investigator bulletin.
ETH.MESH.03086214-219
ETH.MESH.03109341 - Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.
ETH.MESH.03160821 - Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.
ETH.MESH.03160822-823 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.03160827-828 - Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.
ETH.MESH.03162936-938 - Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.
ETH.MESH.03259439-440 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.
ETH.MESH.03361673-689 - 2003 TVT-O Report - Cadaver lab - IFU Device Adequate by Outside surgeon
ETH.MESH.03378923-933 - Prosima Patient Brochure - Stop Coping Start Living
ETH.MESH.03393725-731 - Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract
ETH.MESH.03396246 - VSD Patient Information (Slim Jim) - "Stop Coping Start Living."
ETH.MESH.03427757-759 - EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.
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ETH.MESH.03439842-846 Prosima Sales Aid Training Deck - "What could a truly tension-free repair mean for you and your patients?"
ETH.MESH.03440816-836 - Prosima Revised Webinar Deck - Overview
ETH.MESH.03458123-138 - TTV Patient Brochure
ETH.MESH.03459088-104 - Patient Brochure
ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007
ETH.MESH.03466382-383 - Email string dated 5/12/2011, top one from Kevin Frost to Benjamin Bouterie re: Dr. Bedestani; cc: Stacy Hoffman
ETH.MESH.03471308 - Chart entitled "Pedm Monthly Status."
ETH.MESH.03612364 - Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.
ETH.MESH.03626267-269 - Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.03643392-395 - Email string, top one from Jennifer Paradise to Adrian Roji, et al. re: Approved for distribution: FDA Notification FAQS and Customer Letter.

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ETH.MESH.0370392 - 2007 TVT-Secur (3914_2007-08-22)
ETH.MESH.03715787-793 - Gynemesh PS CER (2002) - Weisberg
ETH.MESH.03715978 - Weisberg email re: TTV question.
ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03751819 - 2009 The Science of What's Left Behind
ETH.MESH.03895925-926 - Email from Frost to Affeld, et al. re: Sales Rep Training on Prosima 5/18
ETH.MESH.03905472-477 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03905968-975 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905992-6000 - Patient Brochure
ETH.MESH.03906001-020 - Patient Brochure: What You Should Know About Pelvic Organ Prolapse. Stop Coping. Start Living. Dated 11/9/2009
ETH.MESH.03906001-020 - Prolift +M Patient Brochure
ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living
ETH.MESH.03907468-469 - Second Generation TTV - by Axel Arnaud
ETH.MESH.03910175 - Email string re - Soft Prolene
ETH.MESH.03910418-421 - Email string re-Mini TTV - mesh adjustment
ETH.MESH.03911107-108 - Email string re-TVT complications (an Prof. Hausler)
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ETH.MESH.03932909-911 - Confidential - History of TTV-O
ETH.MESH.03932912-914 - The History of TTV
ETH.MESH.03941623 - DeLeval Email RE: TTV ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results
ETH.MESH.03962244 - Dear Surgeon letter 7/18/11
ETH.MESH.03984409-410 - Email string, top one from Scott Finley to Greg Prine re: Pelvic Floor Repair Customer Meeting.
ETH.MESH.03989722-723 Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.

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ETH.MESH.03989781-782 - Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.
ETH.MESH.03991591-592 - Memo re: Gynecare Studies; created by Randall Gore.
ETH.MESH.04005090-091 - Ethicon informs FDA of discontinuation
ETH.MESH.04005092-093 - Ethicon's Notification to FDA to Decommercialize
ETH.MESH.04005095-096 - Ethicon's Notification to FDA regarding Decommercialization
ETH.MESH.04042511-512 - Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."
ETH.MESH.04046302 - Powerpoint: TTV and TTV-O Update
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04077172 - Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010
ETH.MESH.04079609 - Gynecare TTV Abbrevio Professional Education (Dr. Babcock).
ETH.MESH.04081189 - Meeting Agenda
ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868 - Email re: 10100080654 and TTV IFUs
ETH.MESH.04181761-762 - Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile
ETH.MESH.04201880 - Prosima Training Deck 2
ETH.MESH.04202101 (2008-448)
ETH.MESH.04206959
ETH.MESH.04381806-819 - Literature Review on Biocompatibility of Prolene Sutures and Impants
ETH.MESH.04427456-457 - FDA Letter re: K063562 Gynecare Prosima Pelvic Floor Repair Systems
ETH.MESH.04474731 - Ethicon's Cover Letter Response to TTV Secur 522 Order
ETH.MESH.04474733 - Ethicon's TTV Secur Postmarket Surveillance Study Plan: {S120095; Gynecare TTV Securm System
ETH.MESH.04476265-272 - April 24 2012 email to FDA
ETH.MESH.04476274-275 - Email re: Meeting Minutes from April 18 2012 meeting w FDA
ETH.MESH.04543334 - Email re: Faculty & Customer Call Post-FDA Panel Mtg on 9/12
ETH.MESH.04543335 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04543335 - Powerpoint "Pelvic Organ Prolapse Surgical Mesh Discussion"
ETH.MESH.04543336 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04548931-935
ETH.MESH.04548975 - Email re: Piet's response to 522 FDA refusal clean
ETH.MESH.04550996-997 - Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD.
ETH.MESH.04551757-795 - E-mail with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM
ETH.MESH.04551946 - Ethicon Gynecare WW Commercialization Decision - US Surgeon Letter 6/1/12
ETH.MESH.04554662 - Ethicon Gynecare WW Commercialization Decision - US Frequently Asked Questions 6/1/12
ETH.MESH.04554687 - FDA letter to Ethicon re 522 Orders (Kanerviko 2013-08-22 29)
ETH.MESH.04556236 - Email re: Piet's takeaways from 2011 FDA meeting
ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010;116:293-303
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ETH.MESH.04567174 - Ethicon Gynecare US Commercialization Decision - US Discussion Guide for Use with Customers 5/15/12
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ETH.MESH.04567677-679 - Frequently asked questions 5/15/12
ETH.MESH.04567680-681 - Message from Laura Angelini to Internal WW Associates 5/15/12
ETH.MESH.04567686-679 - US Sales Call Script for Matt Henderson 5/15/12
ETH.MESH.04567695 - Ethicon Gynecare WW Commercialization Decision - Core Messages 6/1/12
ETH.MESH.04567698 - Ethicon Gynecare WW Commercialization Decision - Standby Statement 6/1/12
ETH.MESH.04567707 - Ethicon Gynecare WW Commercialization Decision - Chuck Austin Message to WW General Surgery Employees 6/1/12
ETH.MESH.04567726 - Ethicon Gynecare WW Commercialization Decision - Tim Schmid message to US General Surgery Employees 6/1/12
ETH.MESH.04568448 - Email re: Piet following 2011 Ad Com
ETH.MESH.04568519 - Email dated 6/8/2012 from Matt Henderson to Tim Schmid re: 522 Communication Recap
ETH.MESH.04568717-718 - Email from Tim Schmid to Chuck Austin dated 6/8/12 re: Prolift +M withdrawal notice
ETH.MESH.04925426 - DX10341 Beath email to Kanerviko
ETH.MESH.04925553-591 - Postmarket Surveillance Study PS120044, Gynecare Prosima™ Pelvic Floor Systems - K063562 dated 2/1/2012
ETH.MESH.04926150-151 - DX24802 - Piet discussing 522 order
ETH.MESH.04926191-192
ETH.MESH.04927339-340 - FDA's Response to Discontinuation Notification-07.09.2012
ETH.MESH.04931596 - Kanerviko email re 40000 page response to 522
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TTV Abbrevio
ETH.MESH.04939001 - Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TTV
ETH.MESH.04941016 - (P041122) Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.04984220-221 - DX24790 - Lucente email
ETH.MESH.05009194
ETH.MESH.05092843 - Chart listing lab schedule for August 11th.
ETH.MESH.05106233-234 - Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder: Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.
ETH.MESH.05164225-226 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.05165675-677 - EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.
ETH.MESH.05217098-100 - FDA Clearance Letter, Modified PROLENE
ETH.MESH.05217103-144 - Letter to FDA re: Notification of Intent
ETH.MESH.05222673-705 - TTV IFU
ETH.MESH.05222686-688 - TTV IFU (4th version) 4.7.06-10.7.08
ETH.MESH.05225354-385 - TTV IFU
ETH.MESH.05225380-384 - TTV IFU - (09.08.00 to 11.26.03)
ETH.MESH.05320909 - 2008 TTV-Secur (2008-135)(38 slides summit)

**Production Materials**

ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05343480-482 - Email string, top one from Joseph Lanza to Bart Pattyson re: Review EWHU IUGA events.
ETH.MESH.05343757-758 - Email string, top one from Kevin Frost to Bart Pattyson re: July 31 Heads Up; cc: Lissette Caro-Rosado.
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05469908-912 - Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05571741 - Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed - Approved: Request for Speaker Event.
ETH.MESH.05573916-917 - Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.
ETH.MESH.05588123-126 - Stephen Wohlert Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05741094 - Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.
ETH.MESH.05741890-891 - Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.
ETH.MESH.05795421-508 - 2001 slides from Parisi binder
ETH.MESH.05795537-599 - 1998 TVT Slide Deck
ETH.MESH.05799233-239 - TVT Exact IFU
ETH.MESH.05799233-316 - TVT-E IFU
ETH.MESH.05820723 - Dear Surgeon Letter re Discontinuation
ETH.MESH.05835298-308 - Pelvic Organ Prolapse - Patient Counseling Guide.
ETH.MESH.05837063-110 - Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.
ETH.MESH.05837242 - DX23938 - Letter re FDA 2011 Notice
ETH.MESH.05840629 - Powerpoint Presentation entitled "Continuum of Education."
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05922038 - Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.
ETH.MESH.05947160-163 - Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up_Gynecare_Reminder; cc: Fernando Nassif, et al.
ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05967586-587 - Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.
ETH.MESH.05987605-606 - Email re: Piet's response to 522 FDA refusal
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06049894-896 - FDA posting FDA Safety Communication: Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse issued 7.13.11
ETH.MESH.06087471-472 - TTVT Patient Brochure
ETH.MESH.06087513-514 - Patient Brochure
ETH.MESH.06113091-092 - Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.

**Production Materials**

ETH.MESH.06124656-657 - Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.
ETH.MESH.06124954-955 - Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.
ETH.MESH.06125000-001 - Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.
ETH.MESH.06125058 - Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.
ETH.MESH.06125098 - Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.
ETH.MESH.06125277 - Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.
ETH.MESH.06125309 - Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.
ETH.MESH.06125502 - Email string, top one from Georgia Long to Bart Pattyson re: may 8th.
ETH.MESH.06151466-467 - Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.
ETH.MESH.06238611 - Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.
ETH.MESH.06255523-534 - Gynecare Prosima Pelvic Floor Repair System: An expert interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the inventor of the Gynecare Prosima system
ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361
ETH.MESH.06388151 - Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints
ETH.MESH.06480608-609 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.06482821-822 Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.
ETH.MESH.06585815 - Powerpoint: Agenda
ETH.MESH.06591558-559 - Email string, top one from Tom Affeld to Shwetal Narvekar re: Pre-launch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06769156 - Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.
ETH.MESH.06887138-140 - Waltregny email written on behalf of Professor de Leval.
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TTVT-O.
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TTVT-O PA
ETH.MESH.06923868-871 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.07105727 - Email string, top one from Laura Vellucci to Colin Urquhart re: Prosima publication.

## Production Materials

ETH.MESH.07189091 - Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.
ETH.MESH.07190144-145 - Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07201006 - Prolift Professional Education Slide Deck (2007)
ETH.MESH.07219196-209 - Clinical Expert Report - Prosima™ signed by David Robinson.
ETH.MESH.07226579-590 - 2000 - TTV CER
ETH.MESH.07229215-245 - Clinical Expert Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.07229312-342 - Clinical Expert Report Gynecare Prosima™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012
ETH.MESH.07246690-719 - Study Report dated May 8, 2012: A systematic review of patient-years of experience in prospective randomized controlled trials (RCTs) in incontinence.
ETH.MESH.07296496 - Chart listing Week Schedule and Lab Flow.
ETH.MESH.07308636-637 - Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc: Lissette Caro-Rosado, et al.
ETH.MESH.07324554-555
ETH.MESH.07351297 - Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>
ETH.MESH.07374762-763 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.07379573-574 Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.
ETH.MESH.07383730-731 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07384790-791 - Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.07462313 - Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response
ETH.MESH.07587090-091 - Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.
ETH.MESH.07628243 - EWH&U Gynecare Prosima™ Pelvic Floor Repair System Faculty Checklist.
ETH.MESH.07630654 - Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.
ETH.MESH.07631488 - Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.
ETH.MESH.07631752-753 - Email string, top one from Eric Globerman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.
ETH.MESH.07631967-968 - Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.
ETH.MESH.07632042 - Event request form for Sepulveda Preceptorship.
ETH.MESH.07632042-043 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.07636090 - Prosima Cadaver Lab Invitation
ETH.MESH.07653362-363 - Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.07903682-683

**Production Materials**

ETH.MESH.07931680-681 - Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.07951163 - Document re: Prosima's apical/anatomical success rates and functional outcomes.
ETH.MESH.07953429-433 - EWH&U 2011 Field Visit Letter
ETH.MESH.07977911
ETH.MESH.08003181-196 - TTV Patient Brochure
ETH.MESH.08003231-246 - TTV Patient Brochure
ETH.MESH.08003247-262 - Patient Brochure
ETH.MESH.08003263-278 - Patient Brochure
ETH.MESH.08003279-294 - TTV Patient Brochure
ETH.MESH.08003295-302 - TTV Patient Brochure
ETH.MESH.08021804-807 - Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.
ETH.MESH.08023741-744 - Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.
ETH.MESH.08033153 - Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Luber, Charles W. Nager, Emily S. Lukacz.
ETH.MESH.08048738-740 - Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.
ETH.MESH.08066452
ETH.MESH.08107354 - Gynecare TTV Tension-free Support for Incontinence: Professional Education Slides
ETH.MESH.08117473 - 2012 TTV-Exact Updated Prof Ed Slide Deck w Production Cover
ETH.MESH.08117625-626 - Prolift +M Profession Education Slide Deck
ETH.MESH.08135444 - Gynecare Prosima - Pelvic Floor Repair System Proctorship
ETH.MESH.08139049-118 - Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.
ETH.MESH.08156958 - 2002 TTV Advanced Users Forum Presentation
ETH.MESH.08161765 - Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.
ETH.MESH.08169582-620 - Surgical Practice of POP survey on Survey Monkey.
ETH.MESH.08290691
ETH.MESH.08299913-917 - (P045678) Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08307644-645 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).
ETH.MESH.08309057-092 - Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."
ETH.MESH.08315779-810 - Clinical Expert Report Gynecare Prolift +M™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012
ETH.MESH.08328772-922 - Prosima - Patient Brochure Literature
ETH.MESH.08334244-245 - Email string re-Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.08375158-159 - Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TTV Abbrevio, Prosima, TTV Exact.
ETH.MESH.08384247

## Production Materials

ETH.MESH.08384270 - Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garris.
ETH.MESH.08421628 - Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12
ETH.MESH.08476311 - Cytotoxicity assessment of Ulstem sling
ETH.MESH.08492824 - Strategic Business Team Meeting - Meeting Notes
ETH.MESH.08565137-141
ETH.MESH.08640676 - Jones email 4/04/08 re Prosima update for RBDs
ETH.MESH.08791917
ETH.MESH.08945734-735 - ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."
ETH.MESH.08945742-744 - Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.
ETH.MESH.08945836-840 - Document entitled "Gynecare Prosima Claims List."
ETH.MESH.08948364-365 - Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.
ETH.MESH.08951725-726 - Email string, top one from Tom Affeld to Kevin Frost re: Prosima 2 year summary for eClinical Compendium.
ETH.MESH.08961175-176
ETH.MESH.08962682-683 - Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.
ETH.MESH.08962684-685 - Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.
ETH.MESH.08971152-153 - Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.
ETH.MESH.08971269-270 - Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.
ETH.MESH.08971271-272 - Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.
ETH.MESH.08971309-314 - Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.
ETH.MESH.08988155 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.
ETH.MESH.08988298-417 - EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.
ETH.MESH.09050450 - Memorandum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).
ETH.MESH.09100506 - Prolift Professional Education Slide Deck (2005)
ETH.MESH.09128451 - Chart entitled "Faculty Training."
ETH.MESH.09128545 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11
ETH.MESH.09138054-055 - Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinos, M.D.
ETH.MESH.09142383-384 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.09142511 - (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.

**Production Materials**

ETH.MESH.09144349 - Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.
ETH.MESH.09191424-426 - Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosimma - Urgent; cc: Irene Leslie, Rosangela Ribeiro.
ETH.MESH.09207059 - Chart entitled "Grier."
ETH.MESH.09218452-453 - Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.
ETH.MESH.09264945-946 - Prolene Mesh Re-Design Project
ETH.MESH.09268043-045
ETH.MESH.09283030 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283031 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283032 - Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283033 - Spreadsheet re: Budget Summary
ETH.MESH.09283034 - Spreadsheet re: Integrated Marketing
ETH.MESH.09283035 - Spreadsheet re: Summary
ETH.MESH.09283036 - Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283037 - Spreadsheet re: Budget Summary
ETH.MESH.09283038 - Spreadsheet re: Integrated Marketing
ETH.MESH.09290755 - Spreadsheet re: Q1 2012 Open PO Summary
ETH.MESH.09290760 - Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09290767 - Spreadsheet re: Uterine Health
ETH.MESH.09290769 - Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary
ETH.MESH.09290772 - Spreadsheet re: Budget Summary
ETH.MESH.09300480 - Spreadsheet re: Prosimma All Day
ETH.MESH.09625725-729 - Government Submissions Log Sheet
ETH.MESH.09625731-737 - FDA Letter. re: approved drug application for polypropylene suture.
ETH.MESH.09625816 - FDA letter re: receipt of drug application for polypropylene suture.
ETH.MESH.09625817 - Letter to FDA re: new drug application for Polypropylene Suture.
ETH.MESH.09629447-448 - FDA Labeling Approval for Prolene
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09630649 - FDA Letter re: package insert for Prolene.
ETH.MESH.09634081 - Sections 6 re: adverse effects.
ETH.MESH.09634299-303 - FDA Letter re: approval of PMA supplement.
ETH.MESH.09634318 - Prolene Package Insert.
ETH.MESH.09634662-663 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09634664-688 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744840-845 - Patient Brochure
ETH.MESH.09744848-855 - Patient Brochure
ETH.MESH.09744858-863 - TTV Patient Brochure
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - (P041320) TTV Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study

**Production Materials**

ETH.MESH.09908683-702 - 2003 TVT-O Report - IFU Device packaging Adequate by Outside surgeons
ETH.MESH.09922570-578 - TVTO PA (TOPA) R&D Memorandum of PA Mesh Assessments for TVTO-PA Katrin Elbert Dec.Revision 1
ETH.MESH.10027307-328 - TVT Surgeons Resource Monograph - June 2000
ETH.MESH.10048035-036 - Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.
ETH.MESH.10179518-636 - Clinical Evaluation Report - Gynecare Gynemesh™ PS Nonabsorbable Prolene™ Soft Mesh signed by Piet Hinoul on 04.26.2013
ETH.MESH.10220659 - Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician
ETH.MESH.10224077 - Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.
ETH.MESH.10232708 - Email from Stevan Barendse to Greg Prine re: Prosima targets.
ETH.MESH.10281860 - 2013 Clinical Expertise TVT Prof Ed Slide Deck
ETH.MESH.10281860 - Tension-Free Midurethral Sling: Market Update.
ETH.MESH.10376963
ETH.MESH.10378001-002
ETH.MESH.10384309-310
ETH.MESH.10399553 - Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.
ETH.MESH.10608341-357 - Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima.
ETH.MESH.10686760-771 - Gynemesh PS aFMEA 2013
ETH.MESH.10686833-852 - Risk Management Report (RMR) for Gynemesh PS 2013
ETH.MESH.10817931 - Pelvic Mesh Post-Market Surveillance Orders April 2012
ETH.MESH.10960414 - Email from Christopher O'Hara to Francois Barbe, et al. re: VRT for Prosima.
ETH.MESH.11048537-538 - Prosima E-blast No. 1 "The Proof of Success."
ETH.MESH.11336474-487 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report
ETH.MESH.11448841 - Conference Participant Report 8/25/11
ETH.MESH.11518663-665 - Email string, top one from Melissa Doyle to Arthur Mourtzinos re: Agenda for tomorrow's lab.
ETH.MESH.11522550-551 - Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.
ETH.MESH.11523079 - Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.
ETH.MESH.11524125-128 - Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.
ETH.MESH.11536046 - Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.
ETH.MESH.11538048-049 - Email from Frost to Globerman, et al. re: prosima usage northeast
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.11543719 - Robinson Gynemesh PS Presentation Awareness Module 4.7.04
ETH.MESH.11905619 - Spreadsheet: Prosima Virtual Roundtable Calls &Targets
ETH.MESH.1210987-995 - Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal

**Production Materials**

ETH.MESH.1222075-079 - Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer
ETH.MESH.12831391-392 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12897617-678 - 2013 Clinical Evaluation Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.13314554 - Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.
ETH.MESH.13532200 - Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12
ETH.MESH.13577809-810 - Prosima Virtual RoundTable
ETH.MESH.13582263 - Reisenauer Prosima study
ETH.MESH.13589382 - Prosima Sales Aid 2
ETH.MESH.13589382 - Prosima Sales Aid 3
ETH.MESH.13589382 - Prosima Selling Guide
ETH.MESH.13592561 - Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"
ETH.MESH.13596052 - Prosima Sales Aid 4 (Proof)
ETH.MESH.13600015 - Barber Study - Defining Success After Surgery for POP
ETH.MESH.13618003-004 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.13618029-031 - EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."
ETH.MESH.13622000-070 - Prosima Trainee Deck Distribution
ETH.MESH.13626471 - Prosima Sales Aid 7 (Proof of Success)
ETH.MESH.13627691 - Expert interview with Dr. Carey (clean)
ETH.MESH.13635675 - 2011 B&W POP & SUI Patient Counseling Guide production copy
ETH.MESH.1363575.NATIVE
ETH.MESH.13637531 - Prosima presentation background and development history
ETH.MESH.13645631 - DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.
ETH.MESH.13649510 - Prosima Sales Training Program
ETH.MESH.13650207 - Prosima Sales Aid Brochure (Dance)
ETH.MESH.13670432 - Prosima Key Procedural Steps (double-sided)
ETH.MESH.13697383 - Prosima legal manufacturer Ethicon Sarl
ETH.MESH.13698543 - Prosima Marketing Material Roll-Out Letter.
ETH.MESH.13698840-859 - Bart Pattyson editorial re prof ed bulletin
ETH.MESH.13699623 - Prosima sales training points
ETH.MESH.13699656 - Prosima DVD
ETH.MESH.13699656 - Prosima Sales Rep materials
ETH.MESH.13699656 - Prosima video with Van Drie and Grier.wmv"
ETH.MESH.13699674 - Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.
ETH.MESH.13713001 - Good image of Prosima box
ETH.MESH.13718001 - Prosima Objective Success Learning Guide
ETH.MESH.13718497 - Prosima Patient Brochure 2

**Production Materials**

ETH.MESH.13724290 - Prosima Apical Support Learning Guide
ETH.MESH.13726909 - Prosima Key Points
ETH.MESH.13727241 - Prosima Overview Presentation
ETH.MESH.13733674 - Prosima MRI Image and Sales Aid
ETH.MESH.13756212-218 - Clinical study Finding Discussion for Gynecare Prosima ™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).
ETH.MESH.13756219 - Gynecare Prosima ™ Pelvic Floor Repair System MRI Address
ETH.MESH.13756384 - Prosima Virtual Round Table Trainee Confirmation
ETH.MESH.13756409 - Prosima Virtual Round Table Preceptor Follow-up and Invitation.
ETH.MESH.13756416-417 - Prosima Virtual Round Table Preceptor Confirmation.
ETH.MESH.13869166 - Powerpoint: Mint Project - Pelvic Floor Repair.
ETH.MESH.14427453-455 - FDA Clearance Letter re: K063562 Gynecare Prosima ™
ETH.MESH.14427459-443 - Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.
ETH.MESH.14427562-563 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.14427564-565 - FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)
ETH.MESH.14427567-569 - Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.
ETH.MESH.14427578-561 - Traditionsl 510(k) Premarket Notification Gynecare Prosima ™ Pelvic Floor Repair System.
ETH.MESH.15958178-182 - Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQS and Customer Letter.
ETH.MESH.161953-954 - 10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture Gynecare TVT Obturator System Sales Materials
ETH.MESH.16259973 - Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports
ETH.MESH.16350627-628 - Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.
ETH.MESH.16352932-934 - Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.
ETH.MESH.1751069-094 - 09/07/2009 Safety review: TTV and TTV-O procedures
ETH.MESH.17669942 - Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.17748760-761 - E-mail 4.25.11 from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.1784779-782 - Memo re: TTV-Base & TTV-O Complaint Review for Laser Cut Mesh (LCM) RiskAnalysis
ETH.MESH.1784823-828 - 2006 TTV TVTO Laser Cut Clinical Expert Report
ETH.MESH.1809056-058 - Email re: Important Laser cut mesh update
ETH.MESH.1809080-081 - Memo re: Comparison of Laser-cut and machine-cut TTV Mesh to Meshes from Competetive Devices (BE02004-1641)
ETH.MESH.1815660-664 - Project Mulberry, Preliminary Clinical Diligence Report
ETH.MESH.18844812 - Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse.
ETH.MESH.19308264-265 - Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.
ETH.MESH.19310234-238 - Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TTV-O

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ETH.MESH.222852-863 - 12/15/2003, Gynecare Final Report # 03*0740, TVT Obturator System
ETH.MESH.222899-909 - Clinical Expert Report
ETH.MESH.2236604-609 - TVT Obturator Brochure; "Results, Precision & Proven Mesh"
ETH.MESH.223779-784 - Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3
ETH.MESH.22625140-145 - MDD CAPA # CAPA-003474
ETH.MESH.22631022-2029 - TVT - Response to Section 39 Request, D-1, 1-1002
ETH.MESH.22937156 - Email from Dan Smith re: NG TVT-O NDP - Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny
ETH.MESH.2340504-533 - TTV IFU
ETH.MESH.2340902-908 - TTV O IFU
ETH.MESH.262089-123 - (P114881) Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out
ETH.MESH.3364663-666 - Email from O'Bryan re: ifu
ETH.MESH.3365250-251 - Email from Weisberg re: IFU update
ETH.MESH.341006-011 - 11/11/10 Letter from John Young re: Global Regulatory Strategy for TTV IFU (RMCP15506/E) Update (Part II, RA0001-2010, Rev. 1)
ETH.MESH.3427878-883 - TTV IFU
ETH.MESH.371496-594 - 01/28/98 Letter from FDA re: K974098 TTV System
ETH.MESH.3911390-391 - Email from Arnaud re: Transient Leg Pain with Mulberry
ETH.MESH.3922926-928 - Email re: OR Agenda Tunn
ETH.MESH.3932909-911 - History of TTV-O
ETH.MESH.3934952-967 - Tension-Free Vaginal Obturator Tape (TVOT) - April 30, 2003 - Meeting Report
ETH.MESH.4048515-520 - KOL Interview
ETH.MESH.4384126-165 - Clinical Evaluation Report, Gynecare TTV Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide
ETH.MESH.442825-826 - Email re: TTV Laser Mesh info
ETH.MESH.524746-748 - Email re: TTV Meeting with Agency
ETH.MESH.525573 - Email re: TTV Laser Cut Mesh
ETH.MESH.5315252-265 - Final Report, PSE Accession No. 97-0197, Project No. 16672
ETH.MESH.658177-198 - TTV Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting
ETH.MESH.6696411-419 - Email re: Performance Evaluation of TTV Prolene Blue Mesh
ETH.MESH.6859834-835 - Email re: Laser Cut TTV
ETH.MESH.6878438-439 - Memo re: VOC on new Laser Cut TTV Mesh
ETH.MESH.6882641-642 - Email from O'Bryan re: GYNECARE TTV Obturator System - FDA
ETH.MESH.6886410-411 - Email from Weisberg re: Mulberry
ETH.MESH.7393700 - 05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TTV PhysicianTraining Policy
ETH.MESH.7692905-907 - Email re: Mesh Fraying Dr. EBERHARD letter
ETH.MESH.8003295-301 - Patient Brochure: "Stop coping, start living."
ETH.MESH.8003303-317 - Patient Brochure: "Stop coping, start living."
ETH.MESH.823793-806 - Transobturator Vaginal Tape Inside-Out (TTV-O): From Development to Clinical Experience
ETH.MESH.865069-072 - Email from Dan Smith re: Draft report translated by "Babel fish" <a href="http://babelfish.altavista.com/tr">http://babelfish.altavista.com/tr</a>

**Production Materials**

ETH.MESH.PM.000001 - Prolift Professional Education Videos
ETH.MESH.PM.000002 - TVT-O Procedural Video
ETH.MESH.PM.000006 - Anatomy Videos
ETH.MESH.PM.000007 - Prolift Professional Education Videos
ETH.MESH.PM.000009 - Anatomy Videos
ETH.MESH.PM.000014 - Prolift Professional Education Videos
ETH.MESH.PM.000015 - Prolift Professional Education Videos
ETH.MESH.PM.000019 - Prolift Professional Education Videos
ETH.MESH.PM.000027 - Prolift Professional Education Videos
ETH.MESH.PM.000032 - Prolift Professional Education Videos
ETH.MESH.PM.000033 - Prolift Professional Education Videos
ETH.MESH.PM.000034 - Prolift +M Professional Education Videos
ETH.MESH.PM.000037 - Prolift Professional Education Videos
ETH.MESH.PM.000038 - Prolift Professional Education Videos
ETH.MESH.PM.000039 - Prolift Professional Education Videos
ETH.MESH.PM.000042
ETH.MESH.PM.000045
ETH.MESH.PM.000048 - Prolift +M Professional Education Videos
ETH.MESH.PM.000057 - Anatomy Videos
ETH.MESH.PM.000058 - Prolift Professional Education Videos
ETH.MESH.PM.000059
ETH.MESH.PM.000065 - Prolift Professional Education Videos
ETH.MESH.PM.000068 - Anatomy Videos
ETH.MESH.PM.000075 - Prolift Professional Education Videos
ETH.MESH.PM.000076 - Prolift Professional Education Videos
ETH.MESH.PM.000078 - Prolift Professional Education Videos
ETH.MESH.PM.000083
ETH.MESH.PM.000084
ETH.MESH.PM.000087
ETH.MESH.PM.000088 - Anatomy Videos
ETH.MESH.PM.000089 - Anatomy Videos
ETH.MESH.PM.000090 - Anatomy Videos
ETH.MESH.PM.000092 - Prolift +M Professional Education Videos
ETH.MESH.PM.000093
ETH.MESH.PM.000094
ETH.MESH.PM.000095
ETH.MESH.PM.000096
ETH.MESH.PM.000097
ETH.MESH.PM.000098
ETH.MESH.PM.000130
ETH.MESH.PM.000134 - Anatomy Videos
ETH.MESH.PM.000143
ETH.MESH.PM.000145 - Prolift +M Professional Education Videos
ETH.MESH.PM.000148
ETH.MESH.PM.000151 - Anatomy Videos
ETH.MESH.PM.000154 - Anatomy Videos
ETH.MESH.PM.000156

**Production Materials**

ETH.MESH.PM.000157
ETH.MESH.PM.000170
ETH.MESH.PM.000171
ETH.MESH.PM.000179 - TVT Secur IFU V5e 2005 to disc (Original from Prof Ed DVD)
ETH.MESH.PM.000179 - TVT-Secur Key Tech Points 5.24.2007 (Color Oringinal from Prof Ed DVD)
ETH.MESH.PM.000190 - Prolift Professional Education Videos
ETH.MESH.PM.000192 - Prolift Professional Education Videos
ETH.MESH.PM.000202
ETH.MESH.PM.000246
ETH.MESH.PM.000257
ETH.MESH.PM.000272
ETH.MESH.PM.000273
ETH.MESH.PM.000274
ETH.MESH.PM.000288
ETH.MESH.PM.000303
ETH.MESH.PM.000306
ETH.MESH.PM.000309
ETH.MESH.PM.000316
ETH.MESH.PM.000317
ETH.MESH.PM.000318
ETH.MESH.PM.000319
ETH.MESH.PM.000320
ETH.MESH.PM.000321
ETH.MESH.PM.000322
ETH.MESH.PM.000336
ETH-00254-261 - Patient Brochure Pelvic Organ Prolapse Get the Facts, Be Informed, Make Your Best Decision dated in 2006
ETH-00295-300 - Exh. 10 Gynecare Prolift IFU dated 2004
ETH-00797-829 - 510(k) Notification Gynemesh Prolene™ Soft Nonabsorbable Synthetic Surgical Mesh.
ETH-00807-808 - FDA Clearance letter for Gynemesh soft mesh for pelvic floor repair
ETH-00830-861 - Labeling/Package Insert
ETH-00862-893 - Test Method for the Determinartion of Mesh Burst Strength for Prolene Soft Mesh.
ETH-00894-927 - Medical Literature
ETH-01363-365 - Exh. 15 Letter to Bryan Lisa from Mark M. Melkerson with FDA stamped 5.15.08 re: K071512 Gynecare Prolift with attached 510(k) K071512
ETH-01816-817 - FDA Clearance Letter, Prolene Soft Mesh (K001122)
ETH-02386 - Cossen, M. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results
ETH-02387 - Lucente, V. Prospective clinical assessment of the total vaginal mesh (TVM) Technique for treatment of pelvic organ prolapse - 6 and 12 month results.
ETH-02388 - Amblard, J. From the TVM to the Prolift® (Gynecare): evolution of a technique for prosthetic support to treat prolapse via the vaginal route, concerning a retrospective multicentric series of 794 patients (684 TVM/110 Prolift)
ETH-02653 - Fatton, B. Preliminary results of the "Prolift™" Technique in the treatment of pelvic organ prolapse by vaginal approach: a multicentric retrospective series of 110 patients. IUGA 2006 Athens Non-discussed Abstract 275

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ETH-02750-755 - Hinoul P. A Prospective Study to Evaluate the Anatomic and Functional Outcome of a Transobturator Mesh Kit (Prolift Anterior) for Symptomatic Cystocele Repair. Journal of Minimally Invasive Gynecology (2008) 15, 615-620
ETH-03220-221 - Cosson, M. Preservation of uterus when treating prolapse by Prolift TM does not significantly reduce risk of early post-surgical complications and failures. ABS 89
ETH-03223 - Dedet, B. Transvaginal repair of genital prolapse by the Prolift technique: outcome one year after surgery.
ETH-03227-228 - Dati, S. Prolift vs. Avaulta for transvaginal repair of severe pelvic prolapse
ETH-03568-578 - (03.01.2005) Summary Memo for Revision B of the Gynecare Prolift Design Failure Modes Effects Analysis (dFMEA).
ETH-07153-158 - Gynecare Prolift Clinical Expert Report signed by Charlotte Owens on 01.14.05.
ETH-07247-303 - (03.02.2005) Approvals and Summary Memo for Version A of the Gynecare Prolift Application Failure Modes Effects Analysis (aFMEA).
ETH-07252-281 - Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique
ETH-10437-449 Gynemesh PS IFU
ETH-10505-596 - 2008 Prolift Slide deck
ETH-10977-983 - Gynecare Prolift IFU dated 2009
ETH-18415 - Memo to Hospital Materials Managers & or Directors from Gynecare Worldwide Ethicon dated 10.10.02 regarding Gynecare Gynemesh*PS
ETH-37788-793 - Gynecare Prolift Clinical Expert report
ETH-60188-195 - Hiltunen R. Low-Weight Polypropylene Mesh for Anterior Vaginal Wall Prolapse - A Randomized Controlled Trial. Obstet Gynecol 2007;110:455-62
Ethicon Final Report, PSE Accession No. 00-0035 An Exploratory 91-day Tissue Reaction Study of Polypropylene-Based Surgical Mesh in Rats (PSE Acc. No. 00-0035)
Ethicon Technical Report: Assessment of Competitor Pelvic Floor Repair Meshes, Version 1; Study Number: CPC-2006-0552; JJ-HMREV-00016715
Ethicon Women's Health & Urology — Clinical Compendium — Sales Rep Positioning [ETH.MESH.0011879; ETH.MESH.00093830]
EWHU Faculty and PF User Conference Calls Outline
Exh. 59 - Gynecare Prolift Pelvic Floor Repair System Physician Learner Profile (2 pages)
Guidance for Industry and FDA Staff. "Class II Special Controls Guidnace Document: Surgical sutures; Guidnace for Industry and FDA."
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance. "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."
Gynecare Gynemesh PS a New Mesh for Pelvic Floor Repair Early Clinical Experience dated in 2003 (8 pgs)
Gynecare Gynemesh PS IFU (English Only) LAB-0012266 Rev: 3, released 02.03.15.
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Gynecare Prolift Pelvic Floor Repair System Total, Anterior and Posterior Pelvic Floor Repair Surgical Technique (30 pgs)
Gynecare Prosima - Content for Ethicon360.com
Gynecare Prosima (K063562) Summary of Safety and Effectiveness
Gynecare Prosima updates to ethicon360.com
Gynecare TVT IFU changes redlined, D-6, 1-20
Gynemesh PS 510k Approval File [FDA]
Gynemesh PS and Prolift IFU

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Gynemesh PS Approval File (FDA) Requested August 15, 2007 Folder: K013718 - 131 pages; Summary: Product: GYNEMESH PROLENE SOFT (POLYPROPYLENE) NON ABSORBABLE SYNTHETIC SURGICAL
Gynemesh PS Approval File from FDA website (K013718)
Gynemesh PS white paper - Early Clinical Experience
Gynemesh PS, Prolift or Prosima IFUs.
HMESS.ETH.11642462 - Franchise Regulatory Labeling Guidance
JJM.Mesh.00043703 Response Statement and FAQS - FDA Notification about use of surgical mesh to treat pelvic organ prolapse and stress urinary incontinence
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
K013718 GYNEMESH PS (Ethicon) Corrected SE Letter (07-Nov-2012)
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Letter from FDA re: Postmarket Surveillance (PS) Study: PS120044 (Prosima 522 Order)
Letter to EWHU Field Sales Force from Price St. Hilaire dated 10.23.06 re: criteria for surgeons being trained for Gynecare Prolift (1 pg)
Letters to and from the FDA re: Prolene, Polypropylene Nonabsorbable Surgical Suture, USP.
Librojo updated TVT Declaration (10-23-15) [12 pages]
May 2010 CER for Gynemesh PS signed by David Robinson
McCabe email re - Sheath Sales Tool - 464
Memo to S. Ciarrocca re: Regulatory Strategy - Project D'Art; Rev 3
Mesh Information for Patients with Pelvic Floor Disorders
Mesh POP Gynemesh Prolift Slides
Mesh SUI TVT Slides
MSDS-Marlex Polypropylenes
Notice of Claimed Investigational Exemption for a New Drug (1-125)
Notice of Claimed Investigational Exemption for a New Drug (126-253)
P113785 - De Leval Confidential 2004 Memo
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]
Pelvic Organ Prolapse Patient Counseling Guide
Powerpoint - GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
Powerpoint - Prospective Clinical Assessment of TVM - 1 Year Results
Powerpoint Presentation entitled "Trocars & Pelvic Anatomy: Do They Mix Well?"
Presentation: Non Absorbable Sutures
Professional education materials
Prolift IFUs
Prolift Professional education
Prolift Professional Education Slide Deck (2007)
Prolift Surgeon's Resource Monograph
Prolift Surgical Technique Guide
Prosima Complaints PPM_REV_0103350
Prosima IFU Book
prosima training deck 1
Prosima training deck 2

**Production Materials**

PS120046 A2 - 7.9.12 FDA Response to Ethicon re Gynemesh PS
Published clinical data and RCTs - Ethicon.com - 4204-C
Seven Year Dog Study - T-2263
Slide Presentatopm "Gynecare Prosima ™ Pelvic Floor Repair System
Summary of Saftey and Effectiveness submitted by Bryan Lisa for Gynecare Prolift and Prolift +M stamped 5.15.08 (2 pgs)
Supplement Numbers and Application Dates
Surgeon's Rescourse Monograph for TVT
TVM Prospective 6 month Data
TVT Abbrevo IFU - 01.2015
TVT and TVT-O IFUs
TVT and TVT-O Professional education
TVT Exact IFU - 01.2015
TVT IFU - 01.2015
TVT IFU (7th version) 2015 - Present - from Ethicon website.
TVT Patient Brochure
TVT Patient Brochure - 2015
TVT Surgeon Monographs
TVT, TVT-O, Gynemesh and Prolift IFU
TVT, TVT-O, Gynemesh and Prolift Professional education.
TVT-O la bandelette trans-obturatorie (Photograph)
TVTO Professional education
TVT-Obturator IFU - 01.2015
TVT-R Prof Education Slide Deck
Video titled Prosima Shortened Procedure. Hydrodissection and Dissection.
Video: 2010 Prosima Testimonial for NTM
Wound Closure Manual

**Company Witness Depositions**

<b>Deponent [Date of Deposition]</b>
Angelini, Laura [09.16.2013]
Angelini, Laura [09.17.2013]
Angelini, Laura [11.14.2013]
Arnaud, Axel [11.15.12]
Arnaud, Axel [11.16.12]
Arnaud, Axel [7.19.2013]
Arnaud, Axel [7.20.2013]
Arnaud, Axel [9.25.2013]
Austin, Charles E. - 08.13.2015
Barbolt, Thomas [1.7.2014]
Barbolt, Thomas [1.8.2014]
Barbolt, Thomas [8.14.2013]
Barbolt, Thomas [8.15.2013]
Barbolt, Thomas Ph.D. [10.10.12]
Barbolt, Thomas Ph.D. [10.9.12]
Batke, Boris [8.1.2013]
Batke, Boris [8.2.2013]
Beach, Patricia [6.17.13]
Beath, Catherine [11.8.12]
Beath, Catherine [11.9.12]
Beath, Catherine [3.26.12]
Beath, Catherine [3.27.12]
Beath, Catherine [7.11.2013]
Beath, Catherine [7.12.2013]
Brown, Allison [9.11.13]
Burkley, Dan F [5.22.2013]
Burkley, Dan F [5.23.2013]
Burkley, Daniel [10.2.12]
Butts, Lebron [8.21.14]
Cecchini, Peter [10.22.2013]
Cecchini, Peter [10.23.2013]
Chahal, Ricky [12.10.2014]
Chen, Meng [10.29.2013]
Chen, Meng [10.3.12]
Chen, Meng [10.30.2013]
Chen, Meng [10.4.2012]
Courts, Paul [6.11.15]
Elbert, Katrin [12.23.14]
Elbert, Katrin, Ph.D. [12.23.2014]
Gauld, Judith [11.8.13] [4.27.12]
Grier, Douglas [12.30.2014]
Hart, James [12.20.13]
Hart, James [9.17.13]
Hart, James [9.18.13]
Hellhammer, Brigitte [9.11.2013]
Hellhammer, Brigitte [9.12.2013]

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Henderson, Matthew [8.27.2015]
Hinoul, Piet [01.13.2014]
Hinoul, Piet [01.14.2014]
Hinoul, Piet [01.15.2014]
Hinoul, Piet [6.26.2013]
Hinoul, Piet [6.27.2013]
Hinoul, Piet M.D., Ph.D. [4.5.12]
Hinoul, Piet M.D., Ph.D. [4.6.12]
Hinoul, Piet M.D., Ph.D. [9.18.12]
Hinoul, Piet M.D., Ph.D. [9.19.12]
Holste, Joerg [12.14.12]
Holste, Joerg [12.15.12]
Holste, Joerg [7.29.2013]
Holste, Joerg [7.30.2013]
Horton, Ronald, M. - 07.01.2015
Isenberg, Richard [11.05.2013]
Isenberg, Richard [11.06.2013]
Jones, Gregory R [8.20.2013]
Kammerer, Gene [01.17.2014]
Kammerer, Gene [01.28.2014]
Kammerer, Gene [01.30.2014]
Kammerer, Gene [10.17.12]
Kammerer, Gene [12.03.2013]
Kammerer, Gene [12.05.2013]
Kammerer, Gene [6.12.2013]
Kanerviko, Brian [8.23.13] [8.22.13]
Kirkemo, Aaron [01.06.2014]
Kirkemo, Aaron [01.07.2014]
Kirkemo, Aaron [4.18.12]
Lamont, Dan [4.3.2013]
Lamont, Dan [4.4.2013]
Lamont, Dan [9.10.2013]
Lamont, Dan [9.11.2013]
Lamont, Daniel [4.4.12]
Lamont, Daniel [5.24.12]
Lin, Susan [3.12.2013]
Lin, Susan [3.13.2013]
Lin, Susan [5.2.2013]
Lin, Susan [5.3.2013]
Lin, Susan [8.1.2013]
Lisa, Bryan [12.19.11]
Lisa, Bryan [12.20.11]
Lisa, Bryan A [4.25.2013]
Lisa, Bryan A [4.26.2013]
Luscombe, Brian [7.29.13]
Mahmoud, Ramy [7.15.2013]
Mahmoud, Ramy [7.16.2013]

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Meek, Jonathan [2.24.12] [9.11.12]
Nager, Charles - 06.10.2014 Deposition Testimony
Owens, Charlotte [6.19.2013]
Owens, Charlotte [6.20.2013]
Owens, Charlotte M.D. [9.12.12]
Owens, Charlotte M.D. [9.13.12]
Parisi, Paul [6.6.13]
Peebles, Rhonda [07.16.2014]
Peebles, Rhonda [08.20.2014]
Robinson, David [7.24.2013]
Robinson, David [7.25.2013]
Robinson, David [9.11.2013]
Robinson, David M.D. [3.13.12]
Robinson, David M.D. [3.14.12]
Robinson, David M.D. [8.23.12]
Schmid, Tim - 07.31.2015
Selman, Renee Elayne [6.20.2013]
Selman, Renee Elayne [6.21.2013]
Smith, Dan J [2.3.2014]
Smith, Dan J [2.4.2014]
Smith, Dan J [5.15.2013]
Smith, Dan J [5.16.2013]
Smith, Dan J [6.4.2013]
Smith, Dan J [6.5.2013]
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Smith, Dan J [8.21.2013]
St Hilaire, Price [7.11.13]
Vailhe, Christophe [6.20.13]
Vailhe, Christophe [6.20.2013]
Vailhe, Christophe [6.21.2013]
Volpe, Clifford [2.28.12] [2.29.12]
Walji, Zenobia [3.7.12]
Weisberg, Martin - 11.12.2015 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony
Weisberg, Martin [5.30.2013]
Weisberg, Martin [5.31.2013]
Weisberg, Martin [8.9.2013]
Weisberg, Martin M.D. [5.24.12]
Yale, Mark [4.17.12]
Yale, Mark [5.16.12]
Yale, Mark [8.7.2013]
Yale, Mark [8.8.2013]
Zaddern, Vincenzo [3.27.12] [3.28.12]

## Other Materials

Publicly Available
ABOG Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery (2012)
ACGME Program Requirements for Graduate Medical Education in Female Pelvic Medicine and Reconstructive Surgery
ACOG (2004) Practice Bulletin 5 - Chronic Pelvic Pain - March 2004
ACOG (2005) Practice Bulletin, Number 63, June 2005
ACOG (2007) Committee Opinion: Vaginal "Rejuvenation" and Cosmetic Vaginal Procedures (Number 378)
ACOG (2009) Committee Opinion: Informed Consent (Number 439)
ACOG (2009) Committee Opinion: Patient Safety in Obstetrics and Gynecology (Number 447)
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<b>Testimony</b>
Pence Trial Testimony (Cavness v. Ethicon) - 09.23.2015
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**MDL Wave Cases**

<b>Depositions</b>
Bedestani, Ahmet, M.D. - 05.15.2020
Blaivas, Jerry (Farrell Prolift) - 08.13.2015
Blaivas, Jerry, M.D. (Edwards TTVT-O) - 3.28.2014
Blaivas, Jerry, M.D. (General Plaintiff Expert-Prolift) - 03.02.2016
Blaivas, Jerry, M.D. (General Plaintiff Expert-TVT-S) - 03.03.2016
Blaivas, Jerry, M.D. (TTV General) 9.17.2015
Blaivas, Jerry, M.D. (TTV General) 9.24.2015
Blaivas, Jerry, M.D. (TTV-Abbrevo) 3.6.2016
Carey, Erin (Durham Plaintiff Expert) - 03.07.2016
Elliott, Daniel (Bellew Prolift) - 9.13.2014
Elliott, Daniel (General Plaintiff Expert-TVT-O & TTV-S) - 03.06.2016
Elliott, Daniel (Gross/Wicker/NJ Prolift) 11.15.12
Elliott, Daniel (Gross/Wicker/NJ Prolift) 11.16.12
Elliott, Daniel (Hammons Prolift) - 11.21.2015
Elliott, Daniel (TTV General) 9.26.2015
Galloway, Niall, M.D. (Taylor Plaintiff Expert) - 03.10.2016
Galloway, Niall, M.D. (Durham Plaintiff Expert) - 03.04.2016
Garely, Alan (General Prolift/Prolift+M) - 4.15.16
Garely, Alan (Prolift General) 3.20.2016
Gonzalez, Ricardo, M.D. (Wolfe Plaintiff Expert) - 03.05.2016
Goodyear, Nathan W., M.D. (Shively Plaintiff Expert) - 03.03.2016
Goodyear, Nathan W., M.D. (Taylor Plaintiff Expert) - 03.03.2016
Iakovlev, Vladimir, M.D. (Taylor Plaintiff Expert) - 03.21.2016
Iakovlev, Vladimir, M.D. (TTV General) - 9.11.2015
Karlovsky, Matthew (Olson Plaintiff Expert) - 03.17.2016
Kholi, M.D. Neeraj (General Plaintiff Expert)
Kohli, Neeraj, M.D. (TTV-O General) 3.21.2016
Margolis, Michael (Amsden Plaintiff Expert) - 03.19.2016
Margolis, Michael (Batiste TTV-O) 11.26.2013
Margolis, Michael (Beltz Prolift, TTV-O) - 09.10.2016
Margolis, Michael (Carlino TTV) 11.21.2015
Margolis, Michael (Cederberg TTV, TTV-S) - 04.29.2016
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Margolis, Michael (Ramirez TTV-O) - 10.10.2014
Margolis, Michael (Ramirez TTV-O) - 10.25.2015
Margolis, Michael (Ramirez TTV-O) 3.12.2016
Mays, Jimmy W., Ph.D. (General Plaintiff Expert) - 03.02.2016
Miklos, John (Garcia TTV-S) - 02.06.2015
Miklos, John (TTV-S General) 4.8.16
Ostergard, Donald (Warlick Plaintiff Expert) - 03.22.2016
Ostergard, Donald Gynemesh PS, Prolift, Prolene Soft (General Plaintiff Expert) - 03.09.2016
Ostergard, Donald, M.D. (Bridges Plaintiff Expert) - 03.23.2016
Parisian, Suzanne (Prolift) 3.8.16
Parisian, Suzanne (TTV-S General) 3.8.16
Pence, Peggy - (Cavness Expert) - 08.20.2015
Pence, Peggy (General) 3.9.2016

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Porter, William, M.D. (General) - 06.15.2016
Porter, William, M.D. (Shively Plaintiff Expert) - 03.13.2016
Priddy, Duane, Ph.D. (General Plaintiff Expert) - 03.08.2016
Raybon, Brian (Prolift/Prolift+M) 4.18.2016
Reeves, Keith (Wolfe Plaintiff Expert) - 03.16.2016
Rosenzweig, Bruce (Adkins TVT Secur) - 02.22.2017
Rosenzweig, Bruce (Carlino) 1.13.2016
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Rosenzweig, Bruce (Engleman) 1.17.2017
Rosenzweig, Bruce (Huskey/Edwards) 3.24.2014
Rosenzweig, Bruce (Jasso Prosima) - 07.14.2016
Rosenzweig, Bruce (Jasso) - 07.14.2016
Rosenzweig, Bruce (Lewis) 11.04.2013
Rosenzweig, Bruce (Long Plaintiff Expert) - 03.10.2016
Rosenzweig, Bruce (Magee) 2.04.2016
Rosenzweig, Bruce (Perry) 12.15.2014
Rosenzweig, Bruce (Ramirez TTV-O) - 10.11.2014
Rosenzweig, Bruce (Ramirez) 3.31.2016
Rosenzweig, Bruce (Susan Smith) 8.31.2016
Rosenzweig, Bruce (TVT General) 9.22.2015
Shobeiri, Abbas (Prolift General) - 8.24.2016
Shobeiri, Abbas (TVT-O) 2.27.2016
Shull, Robert, M.D (Dimock Plaintiff Expert) - 03.15.2016
Shull, Robert, M.D (Prolift/Prolift+M General) - 3.15.2016
Veronikis, Dionysios (Gynemesh PS General) 4.30.2016
Veronikis, Dionysios (TVT General) 4.30.2016
Wilson, Anne (General Plaintiff Expert) - 03.22.2016
Zipper, Ralph (General Prosima, Prolift, Prolift+M) 3.20.2016
Zipper, Ralph (Hammons Prolift) 9.26.2015

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Blaivas, Jerry (TVT General) - 02.01.2016
Blaivas, Jerry (TVT-O General) - 02.01.2016
Blaivas, Jerry (Wave 4 Prolift General) - 01.17.2017
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Blaivas, Jerry (Wave 4 TVT General) - 01.17.2017
Blaivas, Jerry (Wave 4 TVT-O General) - 01.17.2017
Blaivas, Jerry (Wave 4 TVT-S General) - 01.17.2017
Dunn, Russell (General) - 01.23.2016
Elliott, Daniel (Prolift General)
Elliott, Daniel (TVT General) - 02.01.2016
Elliott, Daniel (TVT Supplemental General) - 01.2017
Elliott, Daniel (TVT-O General) - 02.01.2016
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Elliott, Daniel (Wave 5 TVT-O General) - 05.22.2017
Elliott, Daniel (Wave 5 TVT-S General) - 05.22.2017
Garely, Alan (Prolift General)
Guelcher, Scott (General) - Received 05.05.2016
Guelcher, Scott (Wave 5 General) - Received 07.27.2016
Iakovlev, Vladimir (General) - 01.29.2016
Iakovlev, Vladimir (Wave 10 General) - 02.20.2019
Jordi, Howard (General) - 02.01.2016
Klinge, Uwe (POP General) - 11.17.2015
Klinge, Uwe (TVT General) - 11.16.2015
Kohli, Neeraj (TVT-O General) - 01.2016
Margolis, Michael (TVT General) - 02.01.2016
Margolis, Michael (TVT-O General) - 02.01.2016
Margolis, Michael (Wave 5 TVT General) - 05.21.2017
Margolis, Michael (Wave 5 TVT-O General) - 05.21.2017
Mays, Jimmy (General) - 04.29.2016
Mays, Jimmy (Wave 5 General) - 05.22.2017
MDL Wave 9 and 10 Plaintiff General Reports
Michaels, Paul (General) - 07.01.2016
Miklos, John (TVT-S General) - Received 07.08.2016
Muehl, Thomas (POP General) - 11.16.2015
Muehl, Thomas (TVT General) - 11.17.2015
Ostergard, Donald (Prolift, Gynemesh, Prolene General) - 01.31.2016
Ostergard, Donald (Wave 5 Prolift, Gynemesh, Prolene General) - 05.19.2017
Parisian, Suzanne (Jacob General) - 05.22.2016
Parisian, Suzanne (Prolift +M) - served 02.01.2016
Parisian, Suzanne (TVT-S General) - Received 07.08.2016
Pence, Peggy (Notice of Adoption of Prior Reports) - 02.01.2016
Pence, Peggy (Prolift General) - 07.17.2014
Pence, Peggy (Prosima General) - 02.01.2016
Pence, Peggy (Supplemental Prosima General) - 03.03.2016
Pence, Peggy (Supplemental TVT & TVT-O General) - 03.02.2016
Pence, Peggy (Supplemental TVT-O General) - 04.24.2015
Pence, Peggy (TVT General) - 10.14.2013
Pence, Peggy (TVT-O General) - 07.17.2014
Plaintiff expert reports and materials cited in Wave general reports of Rosenzweig, Margolis, Raybon, Blaivas, Ostergard, Shull, Elliott, Zipper, Garely, Kohli, Miklos, Shobeiri and Veronikis
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Priddy, Duane (General)
Raybon, Brian (Prolift General) - 01.26.2016
Raybon, Brian (Wave 12 Gynemesh/Prolift General) - 08.19.2019
Rosenzweig, Bruce (General) - 06.09.2014
Rosenzweig, Bruce (Huskey/Edwards) - 02.21.2014
Rosenzweig, Bruce (Lewis/Brown) - 10.14.2013
Rosenzweig, Bruce (MDL Design Defect) - 08.24.2015
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Rosenzweig, Bruce (Supplemental TVT&TVT-O General) - 01.06.2017
Rosenzweig, Bruce (TVT Abbreviated General) - 01.17.2016
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Rosenzweig, Bruce (Wave 5 TVT Abbreviated General) - 05.22.2017
Rosenzweig, Bruce (Wave 5 TVT Exact General) - 05.22.2017
Rosenzweig, Bruce (Wave 5 TVT General) - 05.22.2017
Rosenzweig, Bruce (Wave 5 TVT-O General) - 05.22.2017
Rosenzweig, Bruce (Wave 5 TVT-S General) - 05.22.2017
Shobeiri, S. Abbas, MD (General Prolift) - 01.29.2016
Shobeiri, S. Abbas, MD (General TVT-O) - 02.01.2016
Shull, Bob (Prolift & Prolift +M General) - 02.01.2016
Shull, Bob (Prosima General) - 02.01.2016
Veronikis, Dionysios (General Gynemesh (and Prolene Soft Mesh) - 01.25.2016
Veronikis, Dionysios (TVT General) - 01.25.2016
Weber, Anne (Prolift General) - 02.01.2016
Wilson, Anne (TVT General) - 01.25.2016
Wilson, Anne (TVT-O General) - 01.30.2016
Wilson, Anne (TVT-S General) - 02.01.2016
Zipper, Ralph (TVT-S General) - 07.27.2017
Zipper, Ralph, MD (General Prolift) - 01.31.2016
Zipper, Ralph, MD (General Prosima) - 02.01.2016

**Barbara Smith - Case Specific**

<b>Depositions</b>
Clark, Amanda L., MD - 6.16.2021
Elliott, Daniel, MD - 08.31.2019
Elliott, Daniel, MD - 4.10.2021
Ritter, Michelle, MD - 4.23.2021
Smith, Barbara L. - 06.18.2019
Smith, Barbara - 12.15.2016
Wheat, Jeffrey, MD - 06.12.2021
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